IN THE HIGH COURT OF SOUTH AFRICA

GAUTENG DIVISION, PRETORIA

CASE NO.: _____/2022

In the application between:

NATIONAL EMPLOYERS' ASSOCIATION OF SOUTH AFRICA (NEASA) Applicant

and

THE MINISTER OF EMPLOYMENT AND LABOUR 1st Respondent

NATIONAL ECONOMIC DEVELOPMENT AND LABOUR COUNCIL (NEDLAC) 2nd Respondent

ADVISORY COUNCIL FOR OCCUPATIONAL HEALTH AND SAFETY 3rd Respondent

THE PRESIDENT OF THE REPUBLIC OF SOUTH AFRICA 4th Respondent

NOTICE OF MOTION

BE PLEASED TO TAKE NOTICE THAT the applicant intends to make application to the above Honourable Court, on a date and time to be arranged with the Registrar, for an order in the following terms:

1 **THAT** the Code of Practice: Managing Exposure to SARS-CoV-2 in the Workplace 2022 (GG 46043) (dated 15 February 2022) published by the first respondent on 15 March 2022 ("the Code"), be declared to be ultra vires, unlawful, unconstitutional and be reviewed and set aside.

2 **THAT** in the alternative to paragraph 1 above, it be declared that sections 2(1)(a), 4, 5(1)(a), 6(1)(c), 10(1), 14, and 17 of the Code are in contravention of the Occupational Health and Safety Act, 1993 ("OHSA") and/or that they, collectively or individually, are declared to be *ultra vires*, unlawful, unconstitutional and be reviewed and set aside

3 **THAT**, in the alternative to paragraph 1 and if the Code is not reviewed and set aside, either *in toto* or in part, it be declared that:

3.1 the Code neither confers an *ex lege* right upon nor imposes an obligation on employers to compel employees to submit to mandatory vaccination against SARS-CoV-2 and/or Covid-19.

3.2 an employer who fails or refuses to implement or enforce against an employee a scheme of mandatory vaccination, employment policy or risk assessment plan that seeks to compel vaccination against SARS-CoV-2 and/or Covid-19, is not in breach of its duties to ensure a safe and healthy workplace;

4 **THAT** it be declared that any scheme of mandatory vaccination, employment policy or risk assessment plan ostensibly authorising any private person or entity to compel an employee to vaccinate against SARS-CoV-2 and/or Covid-19 under threat of loss of employment or under threat of any adverse change of

employment conditions, and absent the voluntary and informed consent of the employee, is unconstitutional, unlawful and invalid.

5 **THAT** it be declared that no employment policy or risk assessment plan is adopted in response to SARS-CoV-2 and/or Covid-19:

5.1 may exclude, derogate from or refuse to recognise and uphold an employee's right to bodily integrity;

5.2 may exclude, derogate from or refuse to recognise and uphold an employee's right to make informed decisions regarding medical treatment;

5.3 may exclude, derogate from or refuse to recognise and uphold an employee's right to refuse to receive medical treatment, including vaccination against or for SARS-CoV-2 and/or Covid-19, if so directed or recommended by an employer;

5.4 may penalise, victimise or dismiss an employee for failing or refusing to receive specific medical treatment, including vaccination against or for SARS-CoV-2 and/or Covid-19directed or recommended by an employer.

6 **THAT** it be declared that the Hazardous Biological Agents Regulations, 2022 (GG46051) ("HBA Regulations") published under the OHSA only finds application in and is limited to circumstances where SARS-CoV-2 is deliberately or incidentally produced, processed, used, handled, stored or transported and not where it may be introduced to the workplace from the community at large or a similar exogenous source.

7 **THAT** it be declared that SARS-CoV-2 which is not deliberately or incidentally produced, processed, used, handled, stored or transported, and which does not arise out of or in connection with the activities of persons at work within the contemplation, scope and ambit of the OHSA, does not constitute a hazard to health and safety arising out of or in connection with the activities of persons at work within the contemplation, scope and ambit of the OHSA.

8 **THAT** section 2(1)(b) of the HBA Regulations be declared:

8.1 to be inconsistent with and *ultra vires* the OHSA, and accordingly invalid; and

8.2 to be constitutionally unlawful, irrational and unreasonable, and accordingly be reviewed and set aside.

9 **THAT**, in the alternative to paragraphs 1 to 8 above, the applicant seeks an order in terms of section 172 of the Constitution that is just and equitable, and which has a remedial effect alleviating the Constitutional infringements, concerns and/or invalidities underlying this application.

10 **THAT**

10.1 the first respondent pays the costs of this application, such costs to include the costs consequent upon the employment of two counsel where so employed, and,

10.2 in the event of opposition by any other respondent, that such respondent be directed to pay such costs jointly and severally with the first respondent, one paying the other to be absolved.

11 **THAT** the applicant be granted such further and/or alternative relief as the Court deems meet.

KINDLY TAKE FURTHER NOTICE that the first, second and third respondents are called upon, in terms of Rule 53(1)(a), to show cause why the aforementioned decisions and/or provisions should not be reviewed and set aside.

KINDLY TAKE FURTHER NOTICE that in terms of Rule 53(1)(b) the first, second and third respondents are requested to dispatch to the Registrar of this Honourable Court, within 15 (fifteen) days after the date of service of this notice of motion on the respondents, the record(s) of all documents relating to and/or relied upon in the making of the decisions and execution of the functions sought to be reviewed, together with such reasons as the first, second and third respondents are by law required or that they desire to give or make.

TAKE FURTHER NOTICE that in terms of Rule 53(4) the applicant may within 10 (ten) days after receipt of the record(s) from the Registrar of this Honourable Court, by delivery of a notice and accompanying affidavit, amend, add to or vary the terms of the notice of motion and supplement the founding affidavit.

TAKE FURTHER NOTICE that the founding affidavits of **GERHARD PAPENFUS**, with attachments thereto, which is annexed to this notice of motion will be used in support of the relief sought herein.

BE PLEASED TO TAKE NOTICE that the applicant hereby appoints the address for service of all processes and documents in this application the address of **KRIEK WASSENAAR & VENTER INC, 13 STAMVRUG AVENUE, VAL DE GRACE, PRETORIA** (reference: **P WASSENAAR / QB0932**) as set out hereunder.

TAKE FURTHER NOTICE that if you intend to oppose this application you are required to:

(a) Within 15 (FIFTEEN) days after date of receipt of this notice of motion or any amendment thereof as contemplated in Rule 53(4), to deliver a notice to the applicant stating that you intend to oppose this application, and in such notice, appoint an address within 15km of the office of the Registrar of this Honourable Court; and

(b) Within 30 (THIRTY) days after expiry of the time period referred to in Rule 53(4), deliver such answering affidavit(s) or other affidavit(s) together with any relevant documents as you may desire in answer to the allegations made by the applicant in the founding affidavit or any amendment or supplementation thereof.

KINDLY TAKE FURTHER NOTICE that if you fail to notify the attorney for the applicant of your intention to oppose the application within 15 (FIFTEEN) days after date of receipt of this notice of motion and/or if you fail to serve and file an answering affidavit within 30 (THIRTY) days after expiry of the time period referred to in Rule 53(4), this application will be set down on the unopposed motion roll on a date to be arranged with the Registrar.

DATED AT PRETORIA ON 17 MAY 2022.

KRIEK WASSENAAR & VENTER INCORPORATED
ATTORNEYS FOR APPLICANT
Third Floor
Hb Forum Building

13 Stamvrug Road
Val De Grace
Pretoria
Tel: 012 756 76566
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melissa@kriekprok.co.za
REF: P.J. WASSENAAR/M JANSEN VAN VUUREN/QB0932

TO: **THE REGISTRAR OF THE ABOVE HONOURABLE COURT**
PRETORIA

AND TO: **THE MINISTER OF EMPLOYMENT AND LABOUR**
FIRST RESPONDENT
Laboria House
215 Francis Baard Street
Pretoria
Gauteng

SERVICE BY SHERIFF

AND TO: **NATIONAL ECONOMIC DEVELOPMENT AND LABOUR COUNCIL (NEDLAC)**
SECOND RESPONDENT
14 Jellicoe Avenue
Rosebank
Johannesburg
Gauteng

SERVICE BY SHERIFF

AND TO: **ADVISORY COUNCIL FOR OCCUPATIONAL HEALTH AND SAFETY**
THIRD RESPONDENT
Laboria House
215 Francis Baard Streets
Pretoria
Gauteng

SERVICE BY SHERIFF

AND TO: **THE PRESIDENT OF THE REPUBLIC OF SOUTH AFRICA**
FIFTH RESPONDENT
Union Buildings
Government Avenue
Pretoria
Gauteng

SERVICE BY SHERIFF

AND TO: **THE STATE ATTORNEY PRETORIA**
316 Thabo Sehume Street
Pretoria Central
Pretoria

SERVICE BY SHERIFF

IN THE HIGH COURT OF SOUTH AFRICA

GAUTENG DIVISION, PRETORIA

CASE NO.: _____/2022

In the application between:

NATIONAL EMPLOYERS' ASSOCIATION OF SOUTH AFRICA (NEASA)	Applicant
and	
THE MINISTER OF EMPLOYMENT AND LABOUR	1st Respondent
NATIONAL ECONOMIC DEVELOPMENT AND LABOUR COUNCIL (NEDLAC)	2nd Respondent
ADVISORY COUNCIL FOR OCCUPATIONAL HEALTH AND SAFETY	3rd Respondent
THE PRESIDENT OF THE REPUBLIC OF SOUTH AFRICA	4th Respondent

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DEPONENT

I, the undersigned,

GERHARD PAPENFUS

state under oath as follows:

1 I am an adult male and the chief executive of the National Employers' Association of South Africa (NEASA), being the applicant in this matter. The applicant has its principal place of business at 3rd Floor, Brooklyn Bridge Office Park, 570 Fehrsen Street, Brooklyn, Pretoria, Gauteng.

2 The facts set out in this affidavit fall within my personal knowledge, save where the context indicates otherwise or has been made known to me in the course of the business of the applicant. Where the contents do not fall within my knowledge, I refer to confirmatory affidavits of persons who possess such knowledge.

3 Where I refer to events of which I do not have such direct knowledge, I pray that the Court admit such hearsay evidence under the applicable provisions of the Law of Evidence Amendment Act 45 of 1988. As will become clear, the factual matrix is unprecedented, and a true and full ventilation of the issues necessitates reference to certain matters beyond my direct experience.

4 I am duly authorised to attest to this affidavit on behalf of the applicant.

5 To the extent that this affidavit contains matters of a legal nature, the applicant relies on the advice of its legal representatives, which I believe to be correct.

THE APPLICANT

6 The applicant is a registered employers association, duly registered in terms of the Labour Relations Act, 66 of 1995 ("LRA"). The applicant functions as an association with separate legal personality from its members.

7 The applicant represents the interests of more than 8000 employers in South Africa.

8 The applicant is also an employer with 85 employees currently in its permanent employ.

9 The applicant aims to proactively empower and promote the interests of employers through labour law services and other labour services that employers may require. In this instance it does so by means of litigation aimed at protecting the rights of its members and of the South African public generally.

10 The applicant is specifically mandated to:

10.1 regulate relations between the applicant's members and their employees and to protect and further the interests of members in relation to their employees;

10.2 to promote the interests of its members in general;

10.3 to promote, support or oppose, as may be deemed expedient, any proposed legislative or other measures, and/or actions affecting the interests of its members;

10.4 to do all such lawful things as may appear to be in the interest of the applicant and its members and which are not inconsistent with the applicant's objectives.

11 I attach hereto as Annexure **X1** an extract of the applicant's Constitution which describes the applicant's objectives. The entire constitution is not annexed in order not to burden the papers unnecessarily but is available to be furnished to any of the respondents on request.

THE RESPONDENTS

12 The first respondent is the **MINISTER OF EMPLOYMENT AND LABOUR**, cited herein in his official capacity. Mr Thembelani Thulas Nxesi currently holds the aforesaid public office, and he is the member of Cabinet responsible for regulating employment relationships in South Africa. The first respondent has his office situated at Laboria House, 215 Francis Baard Streets, Pretoria, Gauteng. I shall refer to the first respondent hereinafter as "**the Minister**".

13 The second respondent is the **NATIONAL ECONOMIC DEVELOPMENT AND LABOUR COUNCIL,** a statutory body with a separate legal personality created in terms of the National Economic, Development and Labour Council Act 35 of 1994 ("NEDLAC Act"). The second respondent has its office situated at 14 Jellicoe Avenue, Rosebank, Johannesburg, Gauteng. The applicant shall refer to the second respondent hereinafter as "**NEDLAC**".

14 The third respondent is the Chairperson of the **ADVISORY COUNCIL FOR OCCUPATIONAL HEALTH AND SAFETY.** According to the information available to the applicant, Mr TIBOR SZANA, currently holds the aforesaid public office. The third respondent is a council in the care of the Department of Employment and Labour, Laboria House, 215 Francis Baard Streets, Pretoria, Gauteng. I shall refer to the third respondent hereinafter as "**the Chairperson**".

15 The fourth respondent is the **PRESIDENT OF THE REPUBLIC OF SOUTH AFRICA**, cited herein in his official capacity. Mr Matamela Cyril Ramaphosa currently holds the aforesaid public office. The fourth respondent is the head of the national executive and Cabinet. He is cited in these proceedings by virtue of the fact that section 85(1) of the Constitution vests the executive authority of the Republic in the President of the Republic. The fourth respondent is joined in the event that he or any member of his Cabinet might have an interest in the litigation currently unknown to the applicant or not foreseen by it. The fourth respondent has his office situated at the Union Buildings, Government Avenue, Pretoria, Gauteng. I shall hereinafter refer to the fourth respondent as "**the President**".

16 A copy of this application will also be served, in respect of the first and fourth, respondents, on the office of the **State Attorney**, Pretoria at 316 Thabo Sehume Street, Pretoria Central, Pretoria, 0001.

17 The second to fourth respondents are cited herein for the interest that they may have in this application. A cost order will only be sought against the second to fourth respondents in the event of unjustified opposition subject to the discretion of the court.

18 The applicant seeks a costs order only against the first respondent.

PURPOSE OF THIS APPLICATION

19 This application is brought in response to the *Code of Practice: Managing Exposure to SARS-CoV-2 in the Workplace 2022 (GG 46043)* published by the first respondent on 15 March 2022 ("**the Code**"). A copy of the Code is attached as Annexure **X2**. The primary purpose of this application is to review and set aside the Code.

20 The Code is erroneously dated 15 February 2022, as explained by the Minister in a press release dated 15 March 2022, attached hereto as Annexure **X3**.

21 According to the press release, the purpose of the Code is:

> *"The code's purpose is to assist employers and employees in managing SARS-CoV-2 exposure in the workplace by guiding employers and employees in conducting or updating a risk assessment in accordance with the Occupational Health and Safety Act, 1993 (Act No 85 of 1993) (OHASA) and Hazardous Biological Agents, 2022 (HBA Regulations) in respect of SARS-CoV-2 exposure, developing a plan to limit infection, transmission, and mitigate the risks of serious illness."*

22 SARS-CoV-2 refers to an alleged novel coronavirus, whereas Covid-19 refers to the disease caused by the SARS-CoV-2 virus. In this affidavit, a reference to the one will usually imply a reference to the other, depending on the context.

23 The Code automatically took "*effect on the date of the lapsing of the Declaration of a National State of Disaster declared under GN313 of 15 March 2020 and extended in terms of section 27(2) of the"* Disaster Management Act 57 of 2002 ("DMA"). This date bears particular significance in terms of the specific purpose of the Code dealt with below.

24 The 'National State of Disaster' was terminated by notice published by the Minister of Cooperative Governance and Traditional Affairs on 15 March 2022. A copy of the notice of termination is attached hereto as Annexure **X4**.

25 The Minister has ostensibly published the Code in terms of section 203(2A) of the LRA, "*after consideration with NEDLAC*".

26 The Code incorporates and applies provisions of the Hazardous Biological Agents Regulations, 2022 (GG46051) published by the Minister on 16 March 2022 ("HBA Regulations") in terms of the Occupational Health and Safety Act, 1993 ("OHSA"), to all employers. A copy of the HBA Regulations is attached hereto as Annexure **X5**.

27 The applicant contends, *inter alia*, the Code:

27.1 obligates all employers to consider and adopt risk assessment plans in response to SARS-CoV-2, which must include measures to be implemented in respect of the vaccination of employees as dealt with below;

27.2 creates a regulatory structure not authorised by Parliament and be suspected to have been embarked upon for undisclosed but predictable political reasons, which:

27.2.1 delegates the authority to mandate vaccination against SARS-CoV-2 to employers;

27.2.2 creates a justification for dismissing employees who refuse to comply with an employer's mandates regarding vaccination.

27.2.3 unlawfully burdens all employers with the obligation to:

(a) infringe upon the constitutional rights of employees;

(b) consider mandatory vaccination policies, despite a general lack of sufficient medical and public health proficiency on the part of the ordinary employer to properly consider the available and ever evolving medical and scientific evidence regarding SARS-CoV-2, Covid-19 and vaccines;

(c) comply with HBA Regulations which are not fit for purpose and are unduly onerous;

28 As such the Code infringes upon the Constitutional rights of employers and employees as envisaged in the relief sought by the applicant. From the facts set out below it is demonstrated that the adoption of the Code and parts of the HBA Regulations are invalid, unlawful, and *ultra vires*.

LOCUS STANDI

29 The applicant has *locus standi* to bring this application:

29.1 in its own interest as a party (as contemplated in section 38(a) of the Constitution) directly affected, as an employer, by the Code and the HBA Regulations;

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

29.3 in the interest of its members (as contemplated in section 38(e) of the Constitution) who as employers are also directly affected by the Code and the HBA Regulations.

30 All other aspects pertaining to the issue of *locus standi* appear from the remainder of this affidavit.

JURISDICTION

31 This Court has jurisdiction to adjudicate this application by virtue of the respondents' principal places of business and administration being situated within the Court's area of territorial jurisdiction.

32 The applicant is furthermore advised that as this matter raises issues of Constitutional rights and that a declaration of invalidity is or may be sought in respect of parts of the relief against natural persons, sections 172, 39(2), and 8(3) of the Constitution find application.

33 The applicant submits that the determination of the issues in dispute regarding the declaratory relief sought in the notice of motion, is not abstract or academic, and the determination thereof will prevent a multiplicity of similar future disputes. It is not the purpose of this application to seek legal advice from the Court.

34 Finally, the applicant has been advised that the principles of subsidiarity and avoidance dictate that aggrieved persons should first seek relief in the statutory and common laws before directly invoking the Constitution in matters involving infringements of the Bill of Rights.

35 This matter involves the infringement of rights for which no subsidiary legal regime has been promulgated and that the issues involved herein are appropriate to the direct application where the development of the common law would not be sufficient.

RELIEF SOUGHT BY APPLICANT

36 The applicant essentially seeks the following relief:

36.1 **THAT** the Code of Practice: Managing Exposure to SARS-CoV-2 in the Workplace 2022 (GG 46043) (dated 15 February 2022) published by the first respondent on 15 February 2022 ("the Code"), be declared to be ultra vires, unlawful, unconstitutional and be reviewed and set aside.

36.2 **THAT** in the alternative to paragraph 36.1 above, it be declared that sections 2(1)(a), 4, 5(1)(a), 6(1)(c), 10(1), 14, and 17 of the Code are in contravention of the Occupational Health and Safety Act, 1993 ("OHSA") and/or that they, collectively or individually, are declared to be ultra vires, unlawful, unconstitutional and be reviewed and set aside

36.3 **THAT**, in the alternative to paragraph 36.1 and if the Code is not reviewed and set aside, either *in toto* or in part, it be declared that:

36.3.1 the Code neither confers an *ex lege* right upon nor imposes an obligation on employers to compel employees to submit to mandatory vaccination against SARS-CoV-2 and/or Covid-19.

36.3.2 an employer who fails or refuses to implement or enforce against an employee a scheme of mandatory vaccination, employment

policy or risk assessment plan that seeks to compel vaccination against SARS-CoV-2 and/or Covid-19, is not in breach of its duties to ensure a safe and healthy workplace;

36.4 **THAT** it be declared that any scheme of mandatory vaccination, employment policy or risk assessment plan ostensibly authorising any private person or entity to compel an employee to vaccinate against SARS-CoV-2 and/or Covid-19 under threat of loss of employment or under threat of any adverse change of employment conditions, and absent the voluntary and informed consent of the employee, is unconstitutional, unlawful, and invalid.

36.5 **THAT** it be declared that no employment policy or risk assessment plan adopted in response to SARS-CoV-2 and/or Covid-19:

36.5.1 may exclude, derogate from or refuse to recognise and uphold an employee's right to bodily integrity;

36.5.2 may exclude, derogate from or refuse to recognise and uphold an employee's right to make informed decisions regarding medical treatment;

36.5.3 may exclude, derogate from or refuse to recognise and uphold an employee's right to refuse to receive medical treatment, including vaccination against or for SARS-CoV-2 and/or Covid-19, if so directed or recommended by an employer;

36.5.4 may penalise, victimise or dismiss an employee for failing or refusing to receive specific medical treatment, including

vaccination against or for SARS-CoV-2 and/or Covid-19 directed or recommended by an employer.

36.6 **THAT** it be declared that the Hazardous Biological Agents Regulations, 2022 (GG46051) ("HBA Regulations") published under the OHSA only finds application in and is limited to circumstances where SARS-CoV-2 is deliberately or incidentally produced, processed, used, handled, stored, or transported and not where it may be introduced to the workplace from the community at large or a similar exogenous source.

36.7 **THAT** it be declared that SARS-CoV-2 which is not deliberately or incidentally produced, processed, used, handled, stored, or transported, and which does not arise out of or in connection with the activities of persons at work within the contemplation, scope and ambit of the OHSA, does not constitute a hazard to health and safety arising out of or in connection with the activities of persons at work within the contemplation, scope and ambit of the OHSA.

36.8 **THAT** section 2(1)(b) of the HBA Regulations be declared:

36.8.1 to be inconsistent with and ultra vires the OHSA, and accordingly invalid; and

36.8.2 to be constitutionally unlawful, irrational, and unreasonable, and accordingly be reviewed and set aside.

36.9 **THAT**, in the alternative to paragraphs 1 to 8 above, the applicant seeks an order in terms of section 172 of the Constitution that is just and

equitable, and which has a remedial effect alleviating the Constitutional infringements, concerns and/or invalidities underlying this application.

36.10 **THAT**

36.10.1 the first respondent pays the costs of this application, such costs to include the costs consequent upon the employment of two counsel where so employed, and,

36.10.2 in the event of opposition by any other respondent, that such respondent be directed to pay such costs jointly and severally with the first respondent, one paying the other to be absolved.

36.11 **THAT** the applicant be granted such further and/or alternative relief as the Court deems meet.

COVID VACCINES

37 The broader circumstances of the global spread of SARS-CoV-2 are well known. In order to avoid prolixity and not to unduly burden the papers, I do not traverse all elements of the outbreak and the government's response to it in minute detail. On 15 March 2020, a 'national state of disaster' was declared in terms of section 27(1) of the Disaster Management Act 57 of 2002 ("DMA").

38 The severity and magnitude of the SARS-CoV-2 virus do not overwhelm the country's health system and has declined to such an extent, consonant with similar actions world-wide, that the 'national state of disaster' has been lifted with effect from 15 March 2022.

39 Since the outbreak of SARS-CoV-2 a global collaborative effort is said to have been embarked upon to develop a vaccine to combat the novel coronavirus. These efforts are alleged to have culminated in the development and distribution of several different vaccines.

40 On 2 December 2020, the United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA) gave temporary regulatory approval for the Pfizer–BioNTech vaccine ("Pfizer vaccine"), thereby becoming the first country to approve the vaccine. By 21 December 2020 many countries and the European Union had authorised or approved the Pfizer vaccine.

41 The various global vaccination development, production, application, and distribution schemes have caused unprecedented global controversy. Issues of safety, efficacy, and allocation have been raised and became political hot potatoes.

42 The issue is extremely divisive, polarising, and far-reaching. It is in many ways a manifestation of the egregious social and cultural divisions in the modern world. It is a topic and phenomenon that cannot be understated for its political import and sheer cultural force. The question of vaccination mandates, or compulsory vaccination, is particularly contested and has led to global civil unrest and litigation.

43 South Africa's vaccination rollout commenced on 18 February 2021 under the auspices, supervision, and drive of the Department of Health. Vaccination approval by the South African Health Products Regulatory Authority (SAHPRA) was accelerated and authorisation for emergency use in terms of section 21 of the Medicines and Related Substances Act 101 of 1965 was granted. SAHPRA

approved the use of the Janssen vaccine ("J&J vaccine") and the Pfizer vaccine, and the Oxford-AstraZeneca vaccine.

44 The rollout of the AstraZeneca vaccine was halted just a few days before it was scheduled to start after it was found not to be efficacious against the 501Y.V2 ('Beta') variant of SARS-CoV-2, and is, to the best of my knowledge, not currently distributed in South Africa.

45 Apparently, the distribution of J&J vaccine was put on hold for certain individuals for two weeks in mid-April 2021 following developments in the United States as the Food and Drug Administration (FDA) warned of, *inter alia*, blood clots as a side-effect. On 5 May 2022 the FDA limited the authorised use of the J&J to certain individuals. A copy of the FDA's press release of 5 May 2022 is attached hereto as Annexure **X6**.

46 Prior to the program's rollout, the President had stated unequivocally that no citizen would be forced to take the vaccination. During an address to the nation on 1 February 2021, the President stated the following:

> *"Nobody will be forced to take this vaccine. Nobody will be forbidden from travelling, from enrolling at school, or from taking part in any public activity if they have not been vaccinated. Nobody will be given this vaccine against their will, nor will the vaccine be administered in secret."*

47 The government's official stance has been against mandatory vaccination. This has seemingly not changed. As recent as 31 March 2022 the Deputy President, David Mabuza, was quoted to confirm before Parliament:

> *"One thing we are not going to do is force people to go and vaccinate,"*
>
> *[...]*

"We think (that) would be crossing the 'red line'. All we can do is encourage our people to go and vaccinate."

I attach the relevant newspaper article as Annexure **X7**.

48 Parliament has shown no legislative intent in support of the issue of mandatory vaccinations. To date no legislation has been tabled to deal with or consider the issue specifically.

49 The Code and the HBA Regulations stand in stark contrast to the government's official stance, as they adopt a position that:

49.1 there is a lawful basis underlying mandatory vaccinations;

49.2 the process of employing mandatory vaccination policies in the workplace requires regulation;

49.3 the dismissal of employees, who refuse to submit to vaccination, is lawful and justified if done in terms of a mandatory vaccination workplace policy.

THE ADOPTION OF THE CODE

50 Section 203 of the LRA prescribes the process to be followed when adopting codes of good practice under the LRA and the legal status that such Codes will hold. It is, therefore, necessary to consider the full text of the section:

"203 Codes of good practice

(1) NEDLAC may

(a) prepare and issue codes of good practice; and

(b) change or replace any code of good practice.

(2) Any code of good practice, or any change to or replacement of a code of good practice, must be published in the Government Gazette.

(2A) The Minister may issue a code of good practice by publishing it in the Government Gazette in accordance with the provisions of this section, if

(a) proposals relating to the code of good practice have been tabled and considered by NEDLAC; and

(b) NEDLAC has reported to the Minister that it has been unable to reach agreement on the matter.

(2B) Subsection (2A) applies to the amendment or replacement of an existing code of good practice.

(3) Any person interpreting or applying this Act must take into account any relevant code of good practice.

(4) A Code of Good Practice issued in terms of this section may provide that the code must be taken into account in applying or interpreting any employment law."

51 According to the proclamation notice for the Code, it was adopted as a code of good practice in terms of section 203(2A) of the LRA:

> *Notice is hereby given that the Code of Good Practice: Managing Exposure to SARS-CoV-2 in the Workplace set out in the Schedule* ***is issued by the Minister of Employment and Labour after consideration by NEDLAC in terms of section 203(2A) of the Labour Relations Act****, 1995 (Act No. 66 of 1995) to take effect on the date of the lapsing of the Declaration of a National State of Disaster declared under GN313 of 15 March 2020 and extended in terms of section 27(2) of the Disaster Management Act, 2002 (Act No.57 of 2002).* [own emphasis]

52 The LRA gives NEDLAC the authority to consider, adopt and publish codes of good practice. In order to adopt a code, a consensus decision must be taken at a meeting of NEDLAC partners. In the absence of consensus, only the Minister may publish a code of good practice.

53 Sections 203(3) and 203(4) confirm that a code of good practice is not merely a policy document with limited legal status. It has binding legal authority similar to regulations and must be considered when interpreting the LRA. It should also be taken into account when applying or interpreting *"any employment law."* Codes of good practice therefore have a direct impact on how employment law is enforced and have direct consequences for employers and employees. Therefore, if a code of good practice confirms that an employer has the right to mandate something, it is axiomatic that employment law must be interpreted to allow for the dismissal of employees who fail to comply with a mandate issued in terms of a code of good practice.

54 From the proclamation notice above, it is clear that the Code is not a code of good practice published by NEDLAC in terms of section 203(1). The Minister adopted it in terms of section 203(2A).

55 In order for the Code to have been lawfully adopted in terms of section 203(2A), the Minister must show that 1) the Code was tabled and considered by NEDLAC and 2) that a report has been received from NEDLAC confirming that its members were unable to reach consensus on the matter.

56 The Minister's proclamation notice confirms that the Code has been considered by NEDLAC but omits to confirm whether there was a lack of consensus amongst

NEDLAC members. The Minister's press release of 15 March 2022 is also silent on the issue.

57 However, during a keynote address at a NEDLAC summit on 7 December 2021, the Minister made various statements alluding to the fact that the NEDLAC partners indeed supported mandatory vaccination policies. The applicant refers to relevant portions of the key-note address as published on the NEDLAC website (a copy is annexed hereto as Annexure **X8**):

> *And Nedlac rose to the occasion – **facilitating an all-of-society response** from the social partners in a number of areas:*
>
> - *Occupational health and safety regulations to safeguard the workplace from Covid-19. The evidence from the Compensation Fund is that the rate of infections in the workplace was much lower than in the community.*
> - *More recently – the social partners have taken up the issue of workplace initiatives to vaccinate employees, **whilst also taking forward the debate on mandatory vaccination.** Indeed, Cabinet referred this matter to Nedlac for input from the social partners. The point must be made that the issue of health and vaccinations goes far beyond the workplace, affecting all communities.*
>
> *[...]*
>
> *These areas remain priorities in particular:*
>
> - ***The finalisation of discussions around mandatory vaccination. I believe that Nedlac has provided clear advice in this regard.** I quote: "The Nedlac social partners represented in the Nedlac Rapid Response Task Team believe that the promotion of vaccines remains the most significant intervention to prevent further spread of Covid19 and lockdowns. To intensify the vaccination programme and in response to the President's call, they have had extensive and urgent*

discussion over the last week and made proposals to the government through the NatJoints that:

- *o **The Health and Safety Direction of the Department of Employment of Labour should be strengthened so that vaccination can become mandatory where a risk assessment at the workplace requires this.***
- *o That access to certain venues, gatherings and events particularly in the hospitality sector should be restricted to vaccinated people only.*
- *o Regulations on maximum capacity of gatherings/venues/events should be simplified, provision of ventilation added and enforcement strengthened so that social distancing can be adhered to.*

*While, the social partners believe that vaccine mandates will pass constitutional scrutiny, they support the work of BUSA to get a declarator from the Constitutional Court in the New Year. **They understand that their proposals will be brought to the attention of the NCCC and other relevant government structures so that decisions can be made speedily to improve the vaccination rate and mitigate the negative impact of a fourth wave."***

58 From the above, it does not seem as if there was a lack of consensus amongst NEDLAC partners regarding the issue of mandatory vaccinations in the workplace. From the Minister's address, it seems as if NEDLAC was indeed making various proposals to Cabinet to ensure that a legal basis for such mandatory vaccinations was created in terms of current labour, health, and safety laws.

59 In a press release following the summit, which is attached as Annexure **X9**, NEDLAC made the following statement:

> *"There is a consensus on the need to promote vaccinations to prevent further lockdown, loss of lives and livelihoods.* ***There is further consensus that vaccinations is an effective way to do this and in the face of Omicron variant, social partners have put proposals to government on mandatory vaccination in workplace and only vaccinated allowed entry."*** *[Own emphasis added]*

60 On 23 March 2022, NEDLAC's executive director, Ms Lisa Seftel, apparently made the following statement on Newzroom Africa:

> *"Nedlac social partners have discussed and agreed on a Code of Good Practice under the Labour Relations Act which sets out what workplaces should do to manage Covid-19"*

61 This statement was confirmed on NEDLAC's official Twitter account. A copy of the post is attached hereto as Annexure **X10**.

62 These statements make it abundantly clear that the Code of Practice published by the Minister in terms of section 203(2A), was indeed approved by NEDLAC partners.

63 The applicant contends that the Minister has acted *ultra vires* his powers under section 203(2A).

CORRESPONDENCE BETWEEN THE PARTIES

64 On 13 April 2022, the applicant directed a letter to the Minster, in which the applicant raised its concerns regarding the lawfulness and enforceability of the Code. A copy of the letter is attached hereto as Annexure **X11**. The applicant contended that:

64.1 the Code and the HBA Regulations as published by the Minister improperly infringe upon the workplace rights of both employees and employers;

64.2 the Code includes salient features that directly and indirectly seek to create a system of mandatory vaccinations in the workplace and legitimise the limitation of the Constitutional rights of persons who choose not to get vaccinated;

64.3 the formulation of the Code is more than a mere guideline to employers regarding the management of SARS-CoV-2 in the workplace, and that it in effect creates a new corpus of labour law that has not previously existed;

64.4 the Minister acted *ultra vires* his powers under section 203(2A) of the LRA;

64.5 the Minister does not have the powers under the LRA to limit any Constitutional rights of employers and/or employees;

64.6 the classification of SARS-CoV-2 as 'a risk group 3' hazardous biological agent ("HBA") under the HBA Regulations is irrational, unreasonable, and *ultra vires*, as SARS-CoV-2 is not a pathogen arising out of or in relation to the workplace;

64.7 the application of the HBA Regulations in the Code is improper as the HBA Regulations are clearly aimed at managing HBA's under an employer's control;

64.8 vaccination does present an irrational and unreasonable means of managing workplace safety;

64.9 that the currently available vaccines 1) do not prevent infection, 2) do not prevent the spread of the virus and 3) do not prevent variants and/or mutations;

64.10 that the available vaccines are not completely safe and that it should therefore not be mandatory;

64.11 that mandatory vaccines infringe upon the Constitutional rights of employees, especially their right to bodily integrity;

65 On 25 April 2022, the Director-General of the Department of Employment and Labour responded to the applicant's letter. A copy of the response is attached as Annexure **X12.** The response confirmed the Minister's position that:

65.1 "the purpose on the published code is just as it states in clause 2 thereof. This code serves to provide guidance to employers and employees in managing exposure to SARS-CoV-2 within the workplace."

65.2 "When one reads clause 2, it is clear that the Minister deemed it necessary for the employers to engage in a risk assessment plan that would determine their response to mitigating the exposure to the SARS-CoV-2 virus within the workplace"

65.3 "In clause 7(2) (c) of the code it is evident that the Minister takes note of the risks associated with the vaccines."

65.4 *"The Minister denies that the code in question imposes compulsory or mandatory vaccinations within the workplace. The Code however, guides employers that wish to resort to mandatory vaccinations in their risk assessment plan as a response to the exposure to the SARS –CoV-2 virus in their workplaces."*

65.5 *"The SARS-Cov-2 is part of the family of Coronavirinae which was included in the list of "Categorization of Biological Agents according to Hazard and Categories of Containment" indicated as Annexure B in the previous Hazardous Biological Agent Regulations (The HBA regulations"). As a result, SARS-CoV2 virus was classified as a hazardous biological agent as defined in the regulations in question."*

65.6 *"Another important consideration that the Minister took into account is the fact that similar to the Mycobacterium tuberculosis, the SARS-Cov-2 can be contracted both from the workplace and outside of the workplace"*

65.7 *"Prior to the publishing the Regulations for HBA regulations Agents the Minister engaged in a widely consultative process that included its publishing for public comment. Further, the Department of Employment and Labour ("the Department") held webinars with stakeholders in order to engage them on the draft HBA regulations."*

65.8 *"After careful considerations of the content of your letter, the Minister has decided not to withdraw the classification SARS-CoV-2 as category risk 3 hazardous biological agent of HBA regulations nor the Code [...]"*

66 The applicant will deal with the Minister's averments in the discussion of the relevant legislation below.

THE CONTENTS OF THE CODE

67 The Code draws its powers not from the LRA whereby it was created, but from the OHSA and its HBA Regulations. In this respect, I refer to the introductory provisions of the Code and specifically paragraphs 1(5) to 1(8), both inclusive.

68 No provision of OHSA provides for or creates a statutory right to compel mandatory vaccinations to be workplace compliant or access a workplace or premises.

69 The limitation of the applicable Constitutional rights and freedoms through an interpretative reading-in exercise is constitutionally unacceptable and contrasts with the rule of law.

SALIENT OBJECTIONABLE FEATURES OF THE CODE

70 It is important to invite attention to the definition of "vaccinated" and "vaccination" in paragraph 3 of the Code. In terms of this definition, it is clear that these definitions mean "fully vaccinated with vaccines and includes additional dose or booster". The practical effect of this is, given trends in current and historical science, that employers and employees will continuously be chasing a moving target which will be impossible to achieve. The impracticality of this provision borders on the absurd in the workplace in terms of control and supervision.

71 I repeat paragraph 50 above. Against these provisions, paragraphs 2(2) and 2(3) of the Code require consideration. The import of obligatory features into the Code is apparent. I quote these for ease of reference:

> *"(2) Another purpose of this Code* ***is to require any person interpreting an employment law to take this Code into account*** *in respect of any matter arising from its application. This includes employees, trade unions, employers, employers' organisations, inspectors, conciliators, arbitrators and judges.*
>
> *(3) To the extent that this Code advances an interpretation of the law, that interpretation is the policy of the Minister and the Department* ***and should be applied unless that interpretation is reversed by a decision of the courts****."* [Own emphasis]

72 Paragraph 2(4) features seemingly contradictory provisions impacting adversely on the requirement of rationality of regulatory provisions, creates undue vagueness rendering the provisions illogical and impractical. It reads as follows:

> *"(4) Apart from those provisions of this Code* ***that reproduce the obligations contained in the employment laws****, the Code is intentionally general because workplaces and their requirements differ. Accordingly departures from the non-obligatory provisions of this Code may be justified in appropriate circumstances.* ***Any employer or employee who departs from them must demonstrate justifiable reasons for doing so.****" [Own emphasis]*

73 With reference to the definition of "HBA Regulations" under paragraph 3 of the Code, I point out that it refers to regulations that did not exist at the time that the Code was promulgated. This is evinced by open spaces in the definition intended to identify the applicable regulations. The only "HBA Regulations" promulgated

in the year 2022 were promulgated subsequently. This definition has not been amended to incorporate by reference the subsequent "HBA Regulations".

74 Paragraph 5 and 14 of the Code makes it obligatory for employers to undertake risk assessments in terms of the OHSA and the HBA regulations, despite the limited application of OHSA and the HBA to certain classes of business. Paragraph 5(1)(b)(i) of the Code obliges the employer to amend its risk assessment plan to include vaccination measures in respect of employees. This includes the dates by which employees must be fully vaccinated.

75 In paragraph 7(2), the Code devolves upon employers the duty to advise employees regarding the nature and risks associated with vaccination. The applicant contends that this delegation is improper and irrational, as the vast majority of employers do not have any medical training. It also subjects employees to the inherent risk of inconsistency between employers regarding the weighing of risks associated with vaccination.

76 Paragraph 12(1)(a) leaves no scope for doubt of the obligation upon employers to notify employees of the obligation to be vaccinated.

77 Paragraphs 8(1)(a),12(2), and 14 compel employers to ensure the disclosure of the vaccination status of employees and compel employees to disclose the information.

78 Paragraph 12(4) renders lip service to the notion of reasonable accommodation of unvaccinated employees upon the strained interpretation of the origin of the HBA, as the Minister would have it.

79 There is a stark contrast between paragraphs 12(4) and 12(6). An employer must accommodate a person who can prove a contraindication to the vaccination, but any other employee can theoretically be dismissed if reasonable accommodation cannot be found. Considering that the motivation for these provisions of the Code is to protect employees from risk emanating from outside of the workplace, the implementation of reasonable accommodation will, in many if not most instances, at least be impracticable and, at worst impossible.

80 Paragraph 19 of the Code allows the Minister to amend the footnotes to the Code if and when he deems it necessary. This will happen online without the requirement of formally amending the Code. It will therefore be expected from employers to vigilantly keep an eye on the website of the Department of Labour to ensure that all new information, as and when it becomes available, is incorporated in its risk plan. It will make the task of having an updated risk plan that, for example, explains the nature of vaccines used in the country, the benefits associated with the COVID-19 vaccines, the contra-indications for vaccination and the nature and risk of serious side effects, as envisaged in regulation 7(2)(c), impossible to maintain.

RELIANCE ON OHSA

81 Neither the Minister, nor any other employer or actor, can lawfully and adequately justify a mandatory vaccination policy under the OHSA.

82 Reliance is placed on sections 8 and 9 of the OHSA, the first of which places a duty on an employer to create and maintain a safe working environment as far as is reasonably practicable, the second of which mandates the same in respect of all other persons who may enter the workplace. This notion has become the

prevailing motivation for those employers who have already commenced implementing workplace vaccination mandates.

83 SARS-CoV-2 is not a problem confined to the workplace only. It is not solely a workplace safety issue that can be attributed to the employer's operations in terms of which the law places a duty on the employer to protect his employees against the potential harms that radiate from the employer's business operations. SARS-CoV-2 is a risk or hazard that emanates from outside the workplace – totally out of the control of any employer. Many other serious health risks or hazards which have been present in our society have never been singled out for similar treatment across the board encompassing all employers in every single sphere of the economy.

84 The heading of OSHA demonstrates its limited scope:

> *"To provide for the health and safety of persons at work and for the health and safety of persons* ***in connection with the use of plant and machinery;*** *the protection of persons other than persons at work* ***against hazards to health and safety arising out of or in connection with the activities of persons at work****; to establish an advisory council for occupational health and safety; and to provide for matters connected therewith." [own emphasis]*

85 OHSA regulates workplace safety. Therefore, interpreting OHSA as requiring a business owner to protect employees against a hazard that does not originate from within the workplace is absurd and could not have been the legislature's intention.

86 The OHSA and the regulations promulgated in terms thereof makes it abundantly clear that the OHSA is specific to industry and work standards. The aim of

OHSA's is to provide for industry or topic-specific regulations which are promulgated in terms of OHSA.

87 There are at present approximately twenty-one such sets of regulations promulgated in terms of OHSA, the vast majority of which are concerned with industries that traditionally involve hazardous work – such as, for example, manufacturing involving heavy machinery or explosives.

88 Of the twenty-one regulations promulgated before March 2022, only one is remotely related to the outbreak of SARS-CoV-2, being the first "*Regulations for Hazardous Biological Agents*" published on 27 December 2001 ("2001 HBA Regulations"). The 2001 HBA Regulations aimed to regulate exposure incidents emanating from workplaces that either handled HBA's as part of their work or otherwise worked with substances or animals from which an HBA could originate. The duty to manage and control an HBA would typically only arise under circumstances where the employer could prevent or control exposure to an HBA in the working environment. Vaccinations as defined in the Code do not prevent exposure.

89 However, the 2001 HBA Regulations focused on mechanical and monitoring interventions that would prevent or contain the spread of an HBA (ventilation systems, health monitoring, protective equipment etc.). It also did not allow or prescribe mandatory medical intervention or vaccination as a prevention measure for an HBA.

90 The 2001 HBA Regulations never envisaged permanent mandatory interventions on the employee.

91 Examples of other sets of regulations published under the OHSA include those dealing with:

91.1 Asbestos

91.2 Lead

91.3 Noise-induced hearing loss

91.4 Electrical installation

91.5 Driven machinery

91.6 Pressure equipment

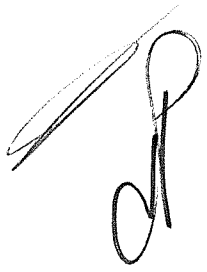
92 The OHSA was designed with a particular type of hazard in mind, which is typically associated with manual labour, industry, and other threat-specific types of work.

93 The applicant was able to discern only two mentions of a 'vaccine' or 'vaccination' contained in the above sets of regulations and codes of good practice:

93.1 the first is an advisory identification of the availability of vaccines for certain specific HBA's in the 2001 HBA regulations;

93.2 the second such recording, again an advisory identification, is found in the *'Code of Good Practice on the Protection of Employees During Pregnancy and After the Birth of a Child'*, which advises that pregnant employees should be immunised against rubella.

94 From the OHSA it appears that the legislature does not:



94.1 expressly limit constitutional rights of employees or delegates to the Minister the power to do so;

94.2 authorise the Minister or afford an employer the power to:

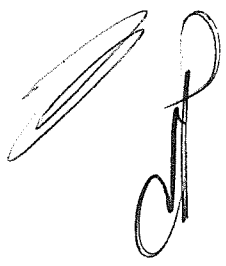
94.2.1 mandate vaccination or medical treatment;

94.2.2 dismiss or otherwise penalise an employee for choosing not to follow a prescribed vaccination or another medical course of treatment.

95 It is the applicant's position that the OHSA neither affords the Minister the power, nor an employer the right, to limit constitutional rights via the vehicle of workplace safety.

96 The limitation of a constitutional right is and at all times should be subject to the most rigid and intensive judicial scrutiny possible. The circumstances under which a limitation of constitutional rights occurs, must be specified. Typically, such limitation is left to the legislature.

97 The power to limit constitutional rights does not lie in the public realm; it is inconceivable that the legislature would have reserved such a power in the OHSA, almost coincidentally reserved for the opportunistic benefit of the Minister. It is equally inconceivable that it was intended to permit an unscrupulous employer to find it and use it to force employees to undergo medical treatment or risk facing dismissal. The legislature would not have hidden an elephant in a mouse hole.



98 Parliament is the only branch of government that may create laws of general application which limit constitutional rights. It is telling that it has not done so concerning mandatory vaccination.

99 The OHSA cannot be utilised to justify mandatory medical interventions in respect of a generalised hazard, especially one which does not arise out of or in connection with the activities of persons at work. The use of section 8 of OHSA to limit almost any constitutional right in response to any hazard that falls within the OHSA's general definition calls for a strained or forced interpretation, which could never have been intended.

100 An interpretative exercise of this nature cannot be permitted to result in the Minister and/or employers being handed a blank chequebook to limit constitutional rights.

101 Even if mandatory vaccination under OHSA is possible, such an interpretative approach will place an extraordinary obligation on employers to deal with any defined hazard originating from outside of the workplace that may fall within OHSA's broad definition. It also grants extraordinary powers to override the constitutional rights of employees. It implies that employers are authorised under the law to act paternalistically and take arbitrary coercive steps against their employees under the guise of ensuring their 'safety' and 'health'.

102 An employer cannot be expected to consider and enforce the mandatory medical treatment of employees in response to hazards that emanate and spread from outside of the workplace. It is also not reasonable to expect of an employer to make decisions regarding the nature of such medical treatment, the benefits and contra-indications, the nature and risk of any serious side-effects thereof in

circumstances where the employer does not have or is unlikely to possess the necessary medical expertise.

103 The OHSA in section 8 imposes a 'reasonably practical' standard as a built-in limitation to the obligations placed on an employer under the act. It ensures a prevention of an overreach by the Minister and employers but for the current objectionable provisions in the Code.

104 The applicant takes issue with the aspect of the imposition of mandatory vaccinations as a 'reasonably practical' measure to ensure a 'safe' and 'healthy' workplace. The applicant challenges the Minister to demonstrate that the Code and HBA Regulations were properly considered, all relevant facts were taken into account, and that a proper cohesive balance was struck.

105 If mandatory vaccinations are deemed to fall within the ambit of a 'reasonably practicable' measure under the OHSA, it will effectively mean that mandatory vaccination policies would be the only workplace measure which will have the effect of a permanent bodily intervention (unlike safety boots, head protection and the like which do not accompany the employee on a permanent basis).

RELIANCE ON HBA REGULATIONS

106 Paragraph 5 (1) (a) of the Code makes is obligatory for an employer to "*undertake a risk assessment to give effect to its obligations under the OHSA and the HBA Regulations.*"

107 Prior to 16 March 2022, regulation 2 of the 2001 HBA Regulations read:

> *"2 Scope of application*

(1) Subject to the provisions of subregulation (2), these Regulations shall apply to every employer and self-employed person at a workplace where

(a) HBA is deliberately produced, processed, used, handled, stored or transported; or

(b) an incident, for which an indicative list is given in Annexure A to these Regulations, occurs that does not involve a deliberate intention to work with HBA but may result in persons being exposed to HBA in the performance of his or her work.

(2) Regulations 8, 14, 15, 16 and 17 shall not apply to an employer or self-employed person at a workplace where the exposure is restricted to a Group I HBA."

108 Regulation 2 of the 16 March 2022 HBA Regulations now reads as follows:

"Scope of application

2 (1) Subject to sub regulation (2), these Regulations apply to every employer or self-employed person at a workplace where –

a) an HBA is produced, processed, used, handled, stored or transported; or

b) exposure to an HBA may occur.

(2) Regulations 8, 14, 15, 16 and 17 do not apply to an employer or self employed person at a workplace where the exposure is restricted to a Group 1 HBA."

109 The distinction between the two provisions is material and substantial. The substituted regulation made provision for an incident or exposure during work, i.e. from within the workplace.

110 The 2022 regulation has unlimited application and includes all exposures of an exogenous source and therefore includes all exposures from outside the

workplace, even exposure not within the control of the employer. The HBA Regulations were created to manage environmental risks in relation to manufactured hazards that are contained to specific areas. The regulations were not designed to regulate viruses which are naturally occurring in the environment.

111 A regulation initially designed for and aimed at potentially hazardous activities has been replaced to be enforced against all workplaces. It's structure and design focusses on manufactured and controlled hazards, but now in terms of the 2022 amendments, are to be applied to almost all risks. The applicant will contend that it would be impossible for a proper risk analysis as envisaged by the HBA Regulations to be conducted within the operational environment of an ordinary workplace.

112 The Minister must indicate on what data he relied in adjusting the HBA Regulations to apply to workplaces that do not directly manufacture or handle hazardous substances.

CONSTITUTIONAL RIGHTS AFFECTED

113 The Code and its application to OHSA and the HBA Regulations infringes upon and restricts various constitutional rights, dealt with below.

114 The applicant contends that the constitutional rights that have been curtailed by the Code and more specifically by means of the implementation of mandatory vaccination policies which will be adopted as a consequence thereof will infringe upon a number of rights, including rights as contained in the Bill of Rights.

DIGNITY

115 The Bill of Rights provides that human dignity and equality are the heart and cornerstone of our constitutional order. The independent right to dignity is found in section 10, which reads as follows:

> *"Everyone has inherent dignity and the right to have their dignity respected and protected."*

116 Since the right to human dignity affirms the intrinsic worth of every person, it is the foundation of several other rights in the Bill of Rights. The right to dignity informs constitutional interpretation and adjudication.

117 The Code makes it acceptable and lawful for an employer to decide that the presence of an unvaccinated employee, in the workplace, presents an unacceptable risk to workplace health and safety.

118 This approach to the vaccination status of an employee, stigmatises unvaccinated persons, who are entitled to have their dignity respected and protected, as threats to others. An unvaccinated person, relying on constitutional rights, is deemed to have made a selfish, and foolish choice and deserving to be excluded from society.

119 It vilifies the employee as someone who is unwilling to accept responsibility and fails to respect the needs and safety of fellow South Africans. As such they are to be removed from workplaces, being arguably the most fundamental important place to be in modern civil society.

120 A narrative has emerged in public discourse branding the unvaccinated as irresponsible and careless. The mandatory vaccination policy enshrined in the

Code legislates that narrative and empowers employers to cast out the unvaccinated. It is dehumanising in that the unvaccinated are moved to the fringes of public life, based solely on an individual choice.

121 Forced exclusions at the election of employers have the effect of stigmatising the unvaccinated. Once this conduct is tolerated and normalised, a pattern of legislated systemic discrimination is allowed to operate against unvaccinated individuals, whereby their enjoyment of fundamental rights and full participation in a society is prohibited. This cannot possibly be considered constitutional. With several rights in the Bill of Rights being affected by a mandatory vaccination policy as allowed in the Code, the vaccination policy strikes at the dignity of the individual in myriad ways. It questions the individual's intelligence, integrity and their ability to make their own decisions in respect of their bodily integrity, whilst other risk mitigating measures are available.

122 Mandatory vaccination policies in general are not pro-choice in that they regard the individual unable to conduct their own risk-benefit analysis between the dangers of SARS-CoV-2 and the potential risks associated with available vaccines.

123 Ngcobo J in the matter of *Barkhuizen v Napier (CCT72/05) [2007] ZACC 5*, stated at paragraph 57 that "*self-autonomy, or the ability to regulate one's own affairs, even to one's own detriment, is the very essence of freedom and a vital part of dignity*". The statement especially applies to the most intimate of matters, such as the right to make your own informed medical decisions.

124 The penalising of a person relying on a fundamental constitutional right offends the principles on which our constitutional democracy is founded. To dismiss an

employee who refuses to get vaccinated penalises the employee because of a constitutional choice made. This is particularly so where the limitation of the right is unreasonable and unjustified because other means to mitigate the possible risks, if any, exist.

125 The Code further legislates that enforcement officers are empowered to ensure proper compliance with the objectives of the Code. Employers, who elect not to enforce mandatory vaccination policies, may thus be penalised for respecting their employees' constitutionally guaranteed choices.

PRIVACY

126 A mandatory vaccination policy compels an employee to disclose personal medical information and her/his vaccination status. This infringes upon the privacy of the employee in circumstances where the limitation is not reasonable or justified. Due to the envisaged requirement of "booster shots" the forced disclosure will become a continual or recurring violation, given that vaccine efficacy varies and wanes over time and also as new variants of SARS-CoV-2 arise.

127 The right to privacy intends to restrain both governmental and private actions that threaten the privacy of an individual. The requirement to disclose intimate medical information infringes directly upon that right. After all, the right to privacy has often been described as the right to be left alone.

128 This right deserves even more protecting considering just how politicised and sensitive the vaccination question has become. It can be compared to the following comparison. It would be unacceptable to require an HIV-positive or TB-

positive person to disclose their status in order for them to access their workplace or any other public environment.

BODILY INTEGRITY

129 The right to bodily and psychological integrity is guaranteed by section 12(2)(b) of the Constitution. It is a component of the broader fundamental rights, which generally deals with 'freedom' and 'security of person'. The relevant text reads as follows:

> *2. Everyone has the right to bodily and psychological integrity, which includes the right -*
>
> *a. to make decisions concerning reproduction;*
>
> *b. to security in and control over their body; and*
>
> *c. not to be subjected to medical or scientific experiments without their informed consent.*

130 It is self-explanatory. This right entails the right of adults to make autonomous decisions regarding their body and psyche. A mandatory vaccination policy limits and violates employees' right to bodily integrity by denying them control over their bodies, with the threat that should they refuse vaccination their livelihoods, opportunity to work and engage in commercial life, will be terminated at the election of an employer. The limitation of the right is again unreasonable and unjustified in an open and democratic society based on human dignity, equality, and freedom.

131 The dispensation of mandatory vaccination of employees by employers under threat of losing their livelihood entrenched in the objectionable mechanisms involved here, is a serious and unacceptable threat to our constitutional

democracy and to the upholding of constitutionally entrenched personal rights. Mandatory vaccination and, moreover, without a sound proven scientific basis, is the thin edge of the wedge that will make a mockery of the Constitution.

FREEDOM OF TRADE AND OCCUPATION

132 A mandatory vaccination policy in the workplace inevitably infringes upon an individual's right to choose their trade, occupation, or profession freely. Failing to be forcefully subjected to vaccinations will invariably lead to a dismissal where a mandatory vaccination policy has been adopted, barring the person to re-enter the same trade, occupation, or profession, unless vaccinated against his/her free will.

133 The fact that section 22 of the Constitution make provision therefore that the practice of a trade, occupation or profession may be regulated by law does not allow an unreasonable or unjustifiable infringement on the choice of the individual. An individual, who exercises control over own body and refuses to subject her/himself to vaccinations or similar medical treatment, ought not thereby be deprived of the individual choice of trade, occupation, or profession.

134 In practice the effect of the Code will be that a system will be created whereby an unvaccinated person can only work at a workplace where such a policy is not in place. This unreasonably and unjustifiably limits commercial opportunity and choice inhibiting or curtailing a person's ability to secure gainful employment.

135 The tacit encouragement of such policies in the Code opens the door for the adoption of similar policies in which employers take it upon themselves to prescribe mandatory medical treatments.

136 A marketplace wherein a certain class of persons are confined to a limited number of places of employment, customers, and potential commercial opportunities - not by virtue of their skill or competence or endeavour - but rather by exclusion based on personal medical choice, does not constitute a democratic society based on human dignity, equality, and freedom.

FREEDOM OF CONSCIENCE, FREEDOM OF RELIGION, BELIEF AND OPINION

137 The situation described above amounts to societal pressure, which has the effect of limiting the right of the unvaccinated person to freedom of conscience, belief, and opinion.

138 Many of my staff and I hold to the sincere, well-founded belief and informed opinion that the available vaccinations have several known and unknown side effects that potentially pose a serious adverse health risk.

139 The applicant, like many other, are of the opinion that vaccination is a personal choice and such held belief or opinion cannot be subjected to mandatory vaccination policies whereby those who hold the belief or opinion are excluded from free and fair choices.

140 A system that effectively penalises people who hold sincere beliefs and opinions regarding the risks and benefits, of recent developed vaccines whereof, the short, medium, and particularly the long-term side-effects remain largely unknown, infringes upon the section 15 rights. This is particularly so where one encounters such a divisive issue as mandatory vaccination. It imperils social cohesion and stability.

141 Mandatory vaccination policies, directly and indirectly, restrict how the beliefs of persons who oppose this type of coercion find expression. Freedom of conscience favours a non-coercive position.

142 In contrast with a non-coercive position, the threat of loss of employment or penalties in the case of a company that refuses to adopt mandatory vaccination policies may eventually become so pressing that persons who oppose mandatory vaccination on moral, religious, and factual grounds act against their conscience and held beliefs or opinions and subject themselves to such infringements.

EQUALITY

143 Discrimination entails differentiation on illegitimate grounds. It is defined in PEPUDA as:

> *"means any act or omission, including a policy, law, rule practice, condition or situation which directly or indirectly- imposes burdens, obligations or disadvantage on; or withholds benefits, opportunities or advantages from any person on one or more of the prohibited grounds*

144 The test of unfairness focuses primarily on the impact of the discrimination on the complainant and others in his or her situation.

LAW OF GENERAL APPLICATION

145 For a law to be of 'general application', it must be sufficiently clear, accessible, and precise so that those who are affected by it can ascertain the extent of their rights and obligations. This is not the case with mandatory vaccinations under the Code premised upon an interpretation of the OHSA. There exists no

legislation or law of general application that supports the notion of mandatory vaccinations. The Code attempts to create the impression that there is already a basis in law for mandatory vaccination policies.

146 Even if this honourable Court should find that the Code or provisions of OHSA amount to 'laws' providing authorisation somehow, neither can be said to be of 'general application'.

147 The attempt to argue that the duty to provide a safe workplace under OHSA clears the way for mandatory vaccination policies is reliant on a farfetched and forced interpretive exercise, which fails to set out in clear language the extent of rights and obligations.

148 Stated otherwise: the mere fact that this application had to be launched is already confirmation that the Code and the legislation on which it purports to rely as a basis in law does not remotely support forced vaccination. There would be no complex attempt to seek support and join the OHSA, HBA Regulations, and the LRA to support the Code if that were the case. The Code unlawfully allows a decision to limit constitutional rights and the exact manner and consequences of that limitation is at a whim of the discretion of private citizens, i.e. employers. Each employer will naturally have different requirements and limitations on the curtailment of rights. The inherent risk of this inconsistency is likely to destabilise and undermine the basic tenets of the rule of law.

149 Even if it is found that the LRA and OHSA provide the Minister with sufficient scope to limit the applicable constitutional rights of unvaccinated persons via regulations or a code of good practice, which the applicant contests, the fact that

significant parts of a decision to limit rights are delegated to private persons, offends the principle of a law of general application.

AGENCY AND DELEGATION

150 The decision to implement a mandatory vaccination policy, to the extent that it may be lawful, must naturally be a legislative function or constitute an executive power to be exercised by an executive organ of state. It cannot be delegated to employers. This is prohibited in terms of section 238 of the Constitution. To leave the decision to mandate vaccinations in the hands of employer's results in the purported 'law' supporting the position that people can be forced to vaccinate, in the arbitrary hands of non-elected members of the public. It constitutes an unlawful delegation of the ostensible authority that, on the erroneous interpretation of OHSA has apparently been delegated by the Minister, to private persons. It cannot conceivably be 'general' in application.

151 If it is found that the right to bodily integrity and freedom of conscience can be limited at the discretion of employers based on public health and workplace safety considerations, it will result in the near-complete hollowing out of those Constitutional rights and the mockery referred to above. Under such a regime, an unqualified employer can force people to undertake an invasive vaccination of his choice, whilst a qualified doctor under our law will be unable to do so without his patient's informed consent.

LIMITATIONS ANALYSIS

152 It is trite that the limitation of a right in the Bill of Rights is permissible in respect of laws of general application but only to the extent that the limitation is

reasonable and justifiable in an open and democratic society based on dignity, equality, and freedom. The advantage and benefit to be gained by limiting the right must be compelling, tangible and substantive.

153 It is equally trite that the limitation must take into account all relevant factors, such as the nature of the right, the importance of the purpose of the limitation, the nature and extent of the limitation, the relation between the limitation and its purpose; and less restrictive means to achieve the purpose.

154 It is apparent that the first respondent did not consider any of these important factors, and if he did, he is challenged to disclose the steps that he took in the limitation exercise. In this regard it is telling that the official stance of the government remains that it has no intention of supporting mandatory vaccinations.

155 Since the advent of the coronavirus less restrictive means, such as testing, masks, etcetera have been widely employed. No evidence exists that the vaccine prevents the spread of the virus. Quite the contrary. It seems generally accepted worldwide and the official policy of government and the stance of many of its medical advisors that the vaccine does not prevent the spread of the virus. The limitation is therefore not justified (whether it be in the Code or any other future attempt to bring about mandatory vaccinations).

156 The simple irrefutable fact is that mandating vaccination does not make the workplace safer.

157 I deal below with evidence that makes it apparent that there is no proportionality between the limitation of the rights set out above and the "perceived" benefit of

mandatory vaccination. It neither provides a "safe workplace" nor protects the health of co-employees.

SARS-CoV-2: OMICRON

158 The Omicron variant is less virulent and far less likely to cause severe disease than any of the variants that came before it. This is demonstrable both anecdotally and with reference to the latest official "credible" scientific data and statistics.

159 Discovered in November 2021, South Africa entered the Omicron-driven fourth wave of infections over the December holiday period of 2021. At that time, the country was at adjusted alert level 1, with barely any severe restrictions on movement and travel aside from the midnight curfew. Despite that fact, the hospital system was not overwhelmed with record numbers of positive cases and testing rates.

160 Prior to that and in November 2021, the country successfully completed a nationwide municipal election without any surge in case numbers. Even though the process was rived with delays, court challenges and technical difficulties, millions of South Africans were thus in close proximity for hours. Despite the fears of the Independent Electoral Commission, who had brought an unsuccessful application to postpone the elections, the largest national public gathering since March 2020 was successful. The applicant refers to the Chief Electoral Officer's report on the 2021 municipal elections published on 13 May 2022, in which he states that 93% of surveyed voters were satisfied that sufficient risk management was in place at voting stations. The report is attached as

Annexure **X13**. The applicant can pause to note that this massive gathering did not differentiate between vaccinated and unvaccinated persons.

161 The fourth wave has now long passed, having reached its peak early January 2022. The country has not been devastated. The return to normality is also evidenced by the 'National State of Disaster' termination on 15 May 2022.

162 The only reasonable inference is that the current SARS-CoV-2 variants are not capable of remotely as much damage – hospitalisation, severe illness, and death - as estimated two years ago.

163 The data further supports this claim. There is a trend of increasing infections paired with decreasing hospitalisation and death. This is clear from the official state-sanctioned data as captured by the National Institute for Communicable Diseases and publicly and freely available. The applicant has tabulated below a comparison of the four waves South Africa experienced. The table below summarises the data from the National Institute for Communicable Diseases ("NICD"), which maintains a daily hospital surveillance report. It illustrates the 7-day moving average positive cases, test positivity peak, and 7-day average death peak across the four waves experienced by South Africa.

Figures taken from date at which highest number recorded	**WAVE I PEAK** (July 13 – Aug 3 2020)	**WAVE II PEAK** (Jan 4 - Jan 13 2021)	**WAVE III PEAK** (July 8 – July 28 2021)	**WAVE IV PEAK** (Dec 18 2021 – Jan 15 2022)
7 DAY MOVING AVERAGE POSITIVE CASES	**12 548**	**18 856**	**20 179**	**23 284**
TEST POSITIVITY PEAK	**28.72%**	**33.68%**	**31.9%**	**60.68%**

HOSPITALISATION PEAK	**ADMITTED** 8319 **ICU**: 1520 **VENTILATOR** 799	**ADMITTED** 17 285 **ICU**: 2407 **VENTILATOR** 1314	**ADMITTED** 17560 **ICU**:2462 **VENTILATOR** 1340	**ADMITTED**: 9379 **ICU**: 722 **VENTILATOR**: 312
7 DAY AVERAGE DEATH PEAK	345	806	520	161

164 SARS-CoV-2 does not currently present a public health risk or workplace hazard which would warrant consideration of a mandatory vaccination policies in the workplace.

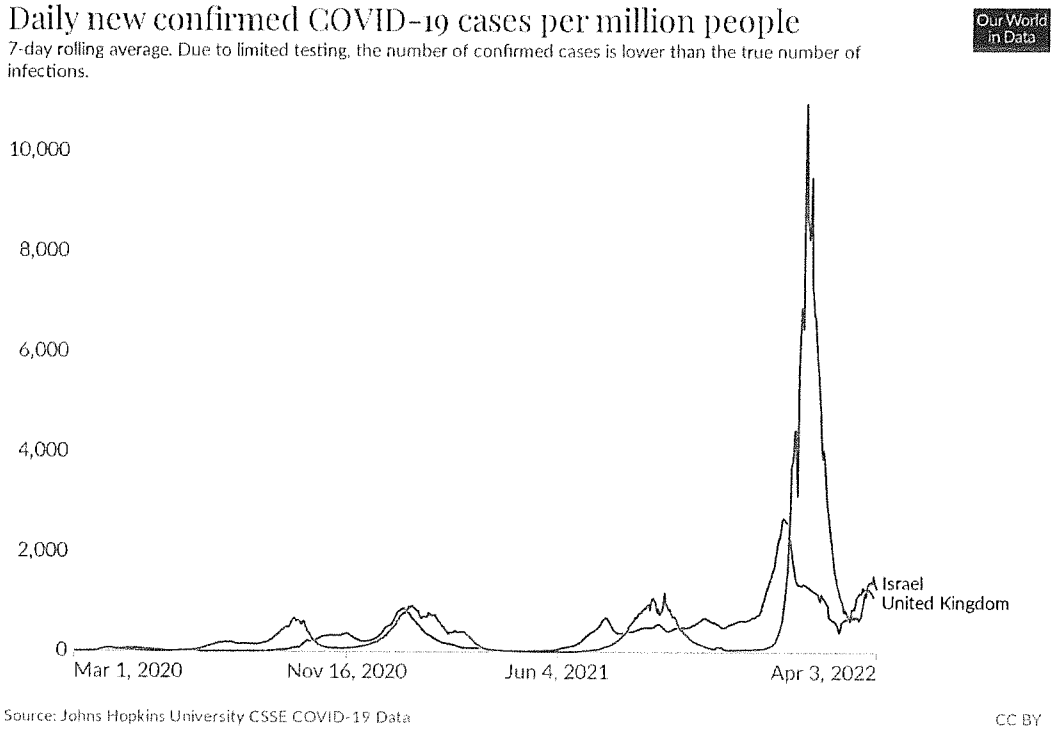
THE VACCINE: NOT EFFECTIVE IN PREVENTING TRANSMISSION AND INFECTION

165 Real-world data from countries with high vaccination levels still indicate high levels of infections. It is impossible to have high levels of infection unless both transmission and infection has taken place amongst the vaccinated. This is confirmed by a UK study done on households that include vaccinated and unvaccinated individuals. Researchers concluded that:

> *"Nonetheless, fully vaccinated individuals with breakthrough infections have peak viral load similar to unvaccinated cases and can efficiently transmit infection in household settings, including to fully vaccinated contacts."*

A copy of the study is attached hereto as Annexure **X14**.

166 Data from Israel, probably the world's most vaccinated country, clearly supports the finding of the above research paper that vaccines do not prevent transmission or infection of SARS-CoV-2.



167 Both the vaccinated and unvaccinated persons spread the virus and become infected. Under those circumstances, any benefit which vaccination might theoretically present, would be to possibly prevent serious disease if a person becomes infected (be it from a vaccinated or unvaccinated person).

168 The value of natural immunity in the fight against SARS-CoV-2 should also not be ignored. A South African study published on 23 February 2022 found:

> *"[P]eak incidences of hospitalization, recorded death, and excess death in the fourth wave were lower than the peak incidences in previous waves. The fourth wave contributed 11.2%, 3.9%, and 3.3% of overall hospitalizations, recorded deaths, and excess deaths due to Covid-19, respectively, whereas the third wave, in which the delta variant was dominant, contributed 43.6%, 49.3%, and 52.7%."*
>
> *"[W]e observed a dramatic decoupling of hospitalizations and deaths from infections during the fourth wave of Covid-19, as compared with the*

proportions seen during the three previous waves. The biologic basis for this decoupling could be the extensive cell-mediated immunity in the population that was induced by previous natural infection and vaccination."

"The researchers found that seropositivity for Covid-19, was prevalent in at least 85% of cases."

A copy of the study is attached hereto as Annexure **X15**.

169 According to Professor Shabir Madhi, the Dean of Health Sciences and professor of vaccinology at the University of the Witwatersrand:

"The omicron wave was associated with 10% of all hospitalisations since the start of the pandemic, whereas 44% of hospitalisations had transpired during the course of the Delta variant wave. More impressively, only 3% of COVID deaths since the start of the pandemic occurred during the omicron wave, compared with 50% during the delta dominant wave."

"Our findings also show that natural infection has been high and is playing a major role in how the pandemic has unfolded especially in countries with low to moderate COVID-19 rollout."

"Another resurgence is likely, and there might well be another variant. But it would be very surprising if further variants are able to evade the T-cell arm of the immune system which is stimulated by vaccines and natural infection."

"So why do I believe that we are at the tail end of this pandemic? It depends what metric you use. If it's about infections, we're not at the tail end. If it's about the number of deaths that will transpire from COVID-19 during 2022, relative to the number of deaths that will transpire from other preventable causes of death in countries such as South Africa, then I believe the country has pretty much arrived towards the end of this pandemic."

> *"In South Africa about 10,000 to 11,000 people die of seasonal influenza every year. In 2019 tuberculosis killed 58 000 in 2019. But we are not declaring an emergency in South Africa to deal with flu or tuberculosis. Deaths from HIV, and complications from HIV, are about 70,000. But South Africa isn't shutting down the country to prevent deaths and infections from these diseases. "*

A copy of the article is attached hereto as Annexure **X16**.

170 The applicant understands that there is some dispute on the data regarding the efficacy and safety of the currently available vaccines. The applicant does not necessarily share the position of the sources stated above in respect of the issue of vaccine safety and efficacy. What is however clear is that most parties agree that vaccines do not prevent infection and transmission – which should lie at the heart of workplace health and safety.

171 A workplace risk analysis cannot rationally differentiate between employees based on their vaccination status.

172 The applicant contends that vaccination will not contribute significantly, if at all, to the creation of a safer working environment. Basing a workplace risk policy on vaccination status is and would be irrational under the circumstances.

MANDATORY VACCINATION POLICIES: CONTRA BONOS MORES

173 The applicant contends that it is against public policy in that there is no justice or morality in coercing an autonomous individual into receiving medical treatment against his will, convictions, and beliefs. This is more important and relevant where such treatment:

173.1 entails potentially severe consequences for the recipient thereof;

173.2 has not been proven to accomplish the goal for which the treatment is mandated;

174 Mandatory vaccinations, which are in any event not "vaccinations" in the true sense of the word, in these circumstances should generally be against the morals and convictions of a society based on mutual respect and dignity. It is against public policy.

175 The currently available data demonstrate that the nation is not in favour of mandatory vaccination or is generally eager to be vaccinated.

176 According to the statistics on the official South African Covid-19 portal administered by the Department of Health (sacoronavirus.co.za), vaccination rates have declined sharply since September 2021. I refer to Figure **Y1** below, drawn from the Covid-19 portal on 7 May 2022, which shows that most South Africans who received vaccinations did so during approximately May 2021 to November 2021. A sharp drop in vaccinations followed during approximately December 2021 – April 2022. According to the website, 49.51% of the population has received the first dose.

177 The data in Figure **Y1** deems a vaccinated person to be a person who has received *"One dose of J&J (single dose regiment) or Pfizer (two dose regiment) first dose administered.*

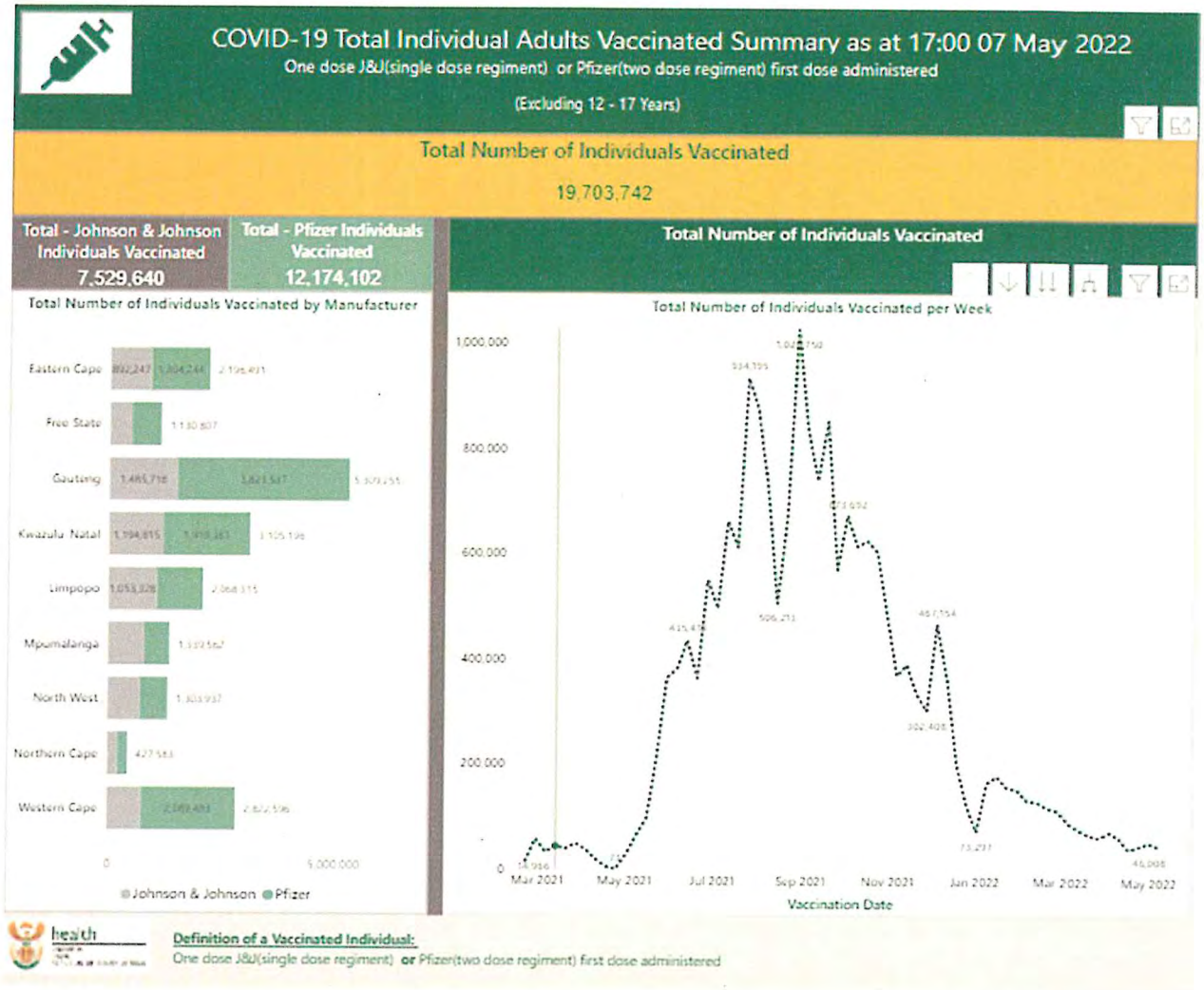


FIGURE **Y1**

178 According to Coronavirus Portal as on 7 May 2022, only 44.9% of persons have been fully vaccinated. Fully vaccinated in this dataset is defined as the total number of individuals with *"One dose of J&J (single dose regiment) or Pfizer (two dose regiment) first & second dose administered.* Refer to Figure **Y2** below.

179 It can be inferred from the difference in vaccination rates between the so-called 'vaccinated' and 'fully vaccinated' datasets published by the government that a large portion of the population has not gone back for a second dose of the two-dose regiment Pfizer vaccine.

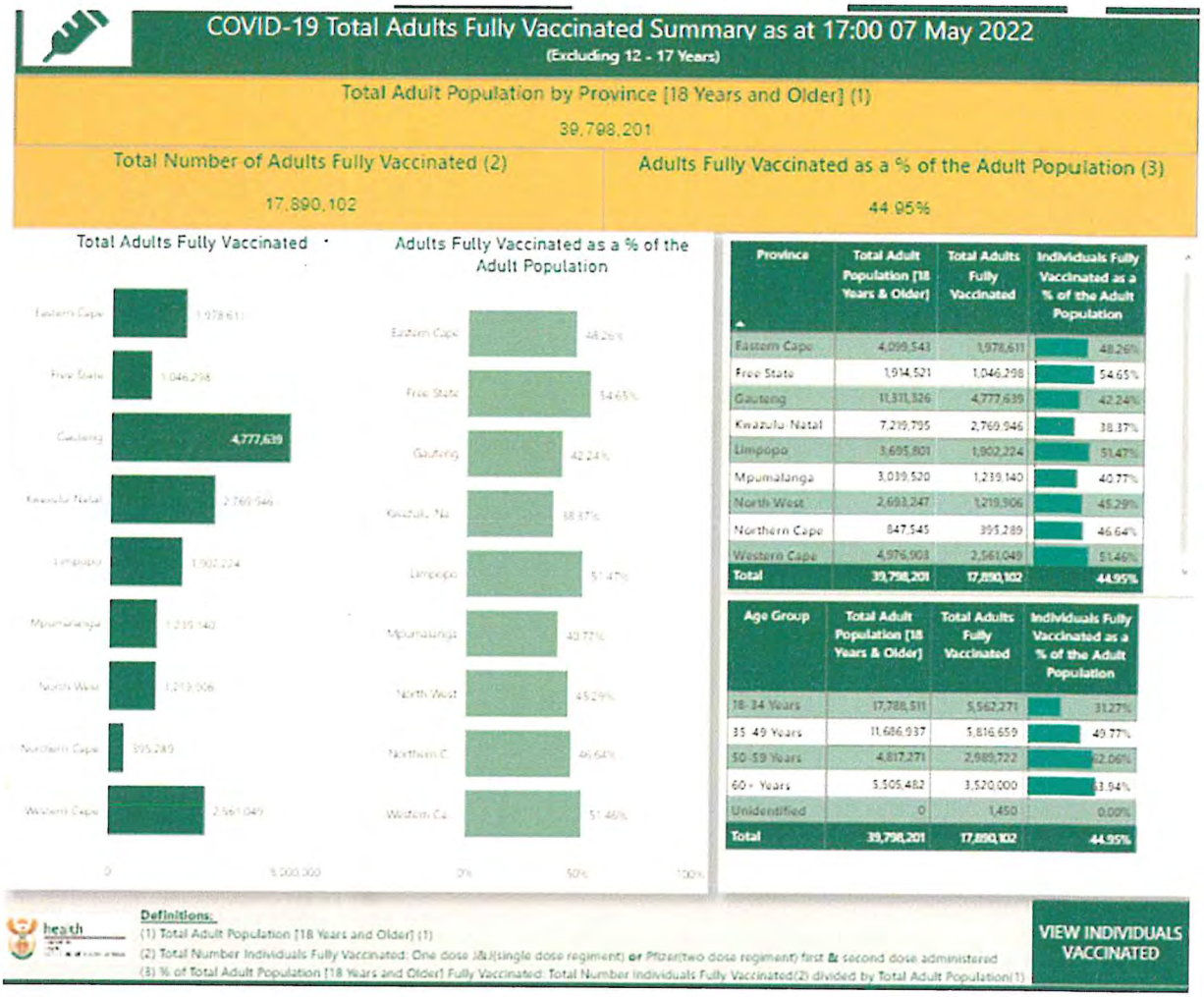


Figure **Y2**

180 According to a circular issued by the National Department of Health, the J&J vaccine booster should be taken after an interval of two months and the Pfizer vaccine booster after an interval of six months. See attached Annexure **X17.**

181 According to the Coronavirus Portal, a total of 9 624 711 persons received one dose of either of the two vaccines by 31 August 2021. Even if we assume that all

of the above people would have become 'fully vaccinated' by the end of November 2021, it will entail that at least a majority of them ought to have been returning for booster shots by the end of May 2022. However, this does not seem to be the case.

182 As of 7 May 2022, 2 836 165 persons have returned to get a so-called 'booster shot' of either of the available vaccines. See Figure **Y3** below. This implies that, at best only approximately 29.46% of persons falling within the August 2021 bracket have returned for booster shots. Considering that many people falling outside of the August 2021 bracket would have qualified for a J&J vaccine booster, the actual number of people from the August 2021 vaccine rush coming back for boosters might be substantially lower.

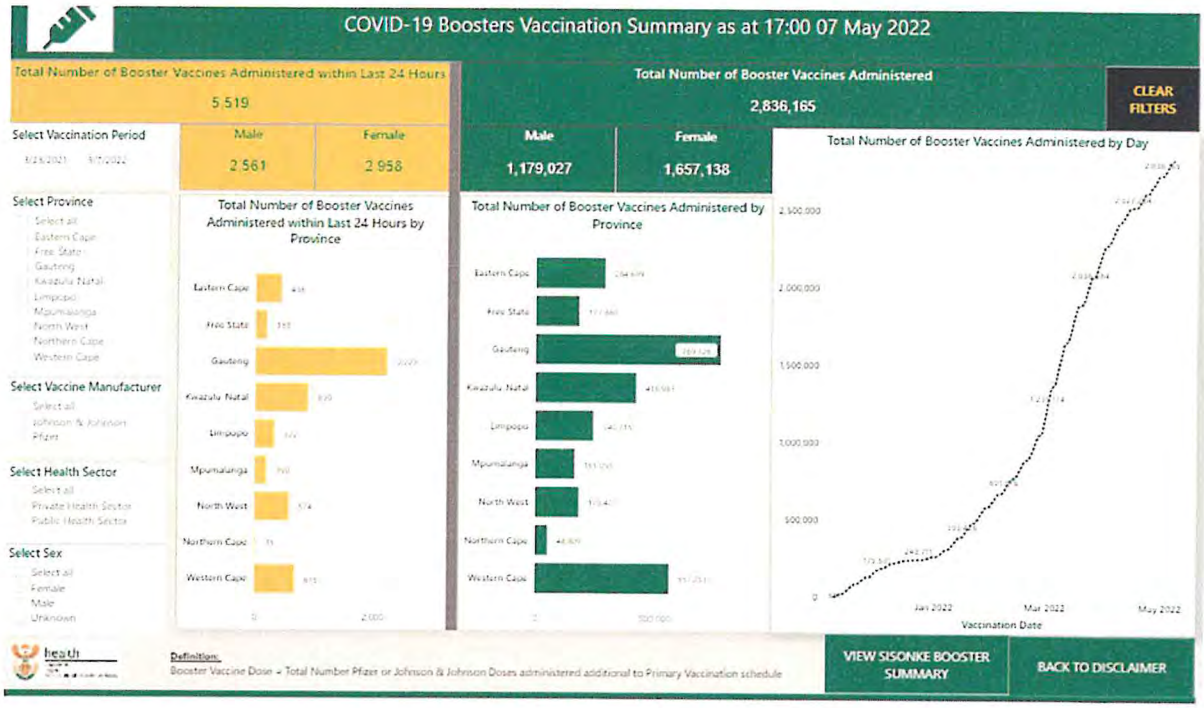


Figure **Y3**

183 The applicant can therefore assume that at least 55.1% of South Africans are deemed to be not 'fully vaccinated'.

184 Considering all of the above, it is clear that the majority of South Africans do not want to submit to any of the current vaccines. This also implies that a majority of the South African workforce, almost a year after the initial vaccine rollout, still does not favour vaccination.

185 In a democratic society, public policy should at least consider the citizenry's voice, especially when considering whether force and coercion should be employed. This should be considered even if the government (or an employer for that matter is convinced that its coercive measures are to the benefit of society.

186 The applicant submits that a mandatory vaccination policy issued in terms of the Code, is therefore *contra bonos mores*.

PUBLIC PARTICIPATION

187 The applicant is unaware of any general consultation process followed by the Minister before publishing the Code, except that consensus was apparently reached between the Minister and the NEDLAC partners.

188 One would assume that a controversial issue such as this would have beseeched the maximum feasible process of public participation by the Minister or at the least NEDLAC before deciding on the Code.

189 Considering the relatively low levels of voluntary vaccination to date, the applicant can only assume that a spirit of paternalistic conviction reigned during the drafting of the Code.

190 The applicant calls on the Minister and NEDLAC to indicate what public participation processes were undertaken during their consideration of the Code.

191 For NEDLAC to purportedly have reached consensus on the topic of the Code, especially considering that more than half of the country is hesitant towards the subject of vaccination, is surprising. NEDLAC is either working directly against the wave of actual public sentiment, or clearly deaf to the pleas of the public.

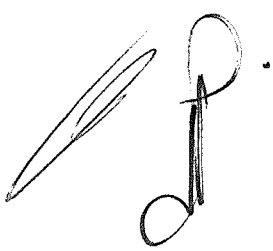
192 In as far as Parliament has created NEDLAC as a forum between government business and labour, it seems as if it has, in this case at least, become an echo chamber that is detached from the views in the country. To consider NEDLAC a forum for public participation, as per its objectives in terms of section 5 of the NEDLAC Act, is to pay lip service to the constitutional right to public participation.

193 The applicant is of the view that the Code has not been drafted with any sufficient public participation on the subject matter.

REQUIREMENTS FOR DECLARATORY RELIEF

194 Declaratory orders can be granted under section 8(1)(d) of the Promotion of Administrative Justice Act ("PAJA"), although PAJA is inapplicable since the applicant deals with the exercise of an executive power. It may be sought under sections 38 and 172(1)(a) of the Constitution. It is also provided for in section 21(1)(c) of the Superior Courts Act 10 of 2013.

195 A proper consideration of the letter of demand issued by the applicant's attorney of record to the Minister and the response thereto evinces a dispute of rights, including dispute in respect of fundamental rights found in the Bill of Rights. To



the extent therefore that the applicant seeks a declaration of rights, each of the empowering provisions finds application.

196 The applicant has purposeful elected to not only limit its relief to a review and setting aside of the Code and the relevant provisions of the HBA Regulations. The applicant also seeks more general declaratory relief so that the OHSA (or any other existing legislation of general application, which is not intended to deal with the consequences of the coronavirus) is not simply again utilised for the purpose of creating codes or regulations that would allow the introduction of mandatory vaccination policies.

197 To that extent the President in his capacity as the head of Cabinet (the executive) has also been joined.

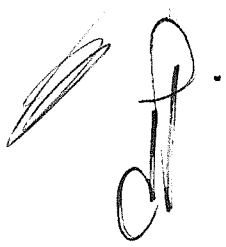
198 Declaratory relief entails the appraisal and determination of a right or obligation as between parties, which right is then considered and pronounced upon by the Court. In order to be granted such relief:

198.1 the Court must be satisfied that the applicant has an interest in an existing, future, or contingent right or obligation, and:

198.2 a justiciable dispute exists in respect of the rights of the parties; and

198.3 should the Court be so satisfied, it must grant a declaration upon the conflicting rights.

199 Such disputes exist and require a pronouncement of this Court in this instance.



200 Remedies and relief in the context of constitutional litigation are often described as "the art of the possible", and this honourable Court must act to address the true underlying dispute to fashion flexible and appropriate relief.

201 The applicant believes that the exposition set out in this affidavit, read with such supplementary affidavits that the applicant may file under rule 53, meet the requirements for the relief sought in the notice of motion.

REVIEW OF DECISION

202 The Code issued by the Minister, falls within the ambit of the exercise of public power. It constitutes a legality review. The exercise of executive power must be lawful. The legislature and the executive in every sphere of government are constrained by the principle that they may exercise no power and perform no function beyond that conferred upon them by law. The preparation and issuing of the Code, similar to the promulgation of regulations, constitute the exercise of public or executive power and necessitates that the decision must meet the requirement of being rational. It must be:

202.1 be rationally connected to a legitimate governmental purpose;

202.2 takes into consideration all relevant information;

202.3 have a rational basis.

203 Furthermore, the decisionmaker must ensure that his/her decisions are lawful and made within the boundaries of the authority granted to him/her. A decision may also not be arbitrary or capricious. The decision must also stand up to constitutional scrutiny.

204 The Minister by his conduct, as already shown above, has failed in his duty to properly administrate the exercise of his powers under the LRA and specifically section 203(2A) thereof.

205 The Minister acted *ultra vires* his powers under the LRA by issuing the Code under circumstances where there appears to have been consensus amongst the NEDLAC partners.

206 Furthermore, there is no rational connection between the objective facts and the decision. This is so on the basis that it should be common cause that vaccinations do not prevent the spread of the virus, either in this instance or in general.

207 The applicant submits that Code as issued by the Minister, should be reviewed, and set aside under both the principles of legality and administrative action.

SUPPLEMENTATION OF PAPERS

208 I am advised that once the Minister has made the required record of his decision available, with such reasons that he is required to furnish or that he may wish to furnish, as is referred to in the notice of motion prefixed hereto, the applicant is entitled to add to or amend the terms of its notice of motion and to supplement its founding affidavit in terms of Uniform Rule of Court 53(4).

CONCLUSION

209 I submit that a proper case has been made (and will have been made out after the first respondent's filing of the obligatory record), for the relief sought in the notice of motion and for an appropriate costs order in the applicant's favour.

210 The applicant seeks the relief and orders as set out in the notice of motion.

GERHARD PAPENFUS

I HEREBY CERTIFY THAT THE DEPONENT HAS ACKNOWLEDGED:

(a) he knows and understands the contents of this affidavit;

(b) he has no objection to taking an oath;

(c) he considers the oath to be binding on his conscience.

THUS signed and sworn before me, at **PRETORIA** on this the 17th day **MAY 2022**, the Regulations contained in Government Notice No. R1648 of 19 August 1977 (as amended) having been fully complied with.

COMMISSIONER OF OATHS

FULL NAMES:

BUSINESS ADDRESS:

DESIGNATION:

JOHANNES JACOBUS VAN DER MERWE
Commissioner of Oaths
HB Forum
13 Stanyrug Street
Val De Grace
Ex Officio Practising Attorney
Republic of South Africa

XI

NEASA

NATIONAL EMPLOYERS' ASSOCIATION OF SOUTH AFRICA

25 April 2018

The Acting Registrar of Labour Relations
Department of Labour
Private bag X117
Pretoria
0001

Madam

Amendment of the constitution of the National Employers' Association of South Africa in terms of section 101 of the Labour Relations Act

This is to certify that at an Executive Committee meeting of the National Employers' Association of South Africa (NEASA) on 23 April 2018, it was resolved to adopt the attached amended NEASA Constitution.

It is further certified that all the provisions of NEASA's constitution relating to the adoption of amendments have been complied with.

Regards

GC Papenfus
CHIEF EXECUTIVE

I HEREBY CERTIFY IN TERMS OF SECTION 101 (3) (a) OF THE ACT THAT THE AMENDMENT TO / REPLACEMENT OF THE CONSTITUTION HAS BEEN REGISTERED ON:-

DATE: 30 MAY 2018

REGISTRAR OF LABOUR RELATIONS

Head Office Tel (012) 622 8971 • Fax (012) 332 4344 • e-mail info@neasa.co.za • www.neasa.co.za
Brooklyn Bridge Office Park, Steven House, 3rd Floor, 570 Fehrsen Street, Brooklyn, Pretoria, 0181
PO BOX 31089, Totiusdal, 0134

Other Offices Bloemfontein, Cape Town, Durban, East London, George, Kimberley, Klerksdorp, Nelspruit, Port Elizabeth, Pretoria, Upington

Executive Committee Chairman JG Grobbelaar, MA Venter, FJ Duvenage, W Louw, HL van Tonder
Chief Executive GC Papenfus

CONSTITUTION OF THE NATIONAL EMPLOYERS' ASSOCIATION OF SOUTH AFRICA (NEASA)

1. NAME AND ADDRESS

The name of the Association shall be the National Employers' Association of South Africa (NEASA).

2. DEFINITION

Any expression used in this constitution which is defined in the Labour Relations Act, 1995 (as amended), shall, unless the contrary intention appears, have the same meaning as in that Act.

3. STATUS AND OBJECTS

3.1. The National Employers' Association of South Africa (NEASA) shall be an association not for gain.

3.2. The objects of the Association shall be:

(a) to regulate relations between members and their employees and to protect and further the interest of members in relation to their employees;

(b) to promote the interests of members in general;

(c) to facilitate settlement of disputes between members and their employees through dialogue and by means of conciliation, mediation, arbitration or litigation;

(d) to promote, support or oppose, as may be deemed expedient, any proposed legislative or other measures and/or actions affecting the interest of members;

(e) to provide, when deemed necessary, assistance to members on matters affecting the relationship between themselves and their employees, including disputes and proceedings before any authority with resolutive powers, and which assistance may include retaining the services and advice of appropriate experts, consultants or legal advisors/specialists as may be appropriate to the issue concerned;

(f) to co-operate with associations of employers and or employees to deal with matters which affect members;

(g) to acquire, either by purchase, or otherwise, any movable or immovable property, and also to sell, let, mortgage or otherwise deal with assets belonging to the Association or use such property for other purposes as the members may approve;

(h) to establish and administer funds for the benefits of its members and their dependants;

(i) to borrow, invest, lend, subscribe or donate money for the furtherance of the objects of the Association;

(j) to use every legitimate means to induce all persons who are eligible for membership to become members;

(k) to affiliate with and participate in the affairs of any international employers' association or the International Labour Organisation (ILO); and

(l) to do such other lawful things as may appear to be in the interests of the Association or its members and which are not inconsistent with the objects or any matter specifically provided for in this constitution.

4. MEMBERSHIP

4.1. Any employer in the Republic of South Africa shall be eligible for membership of the Association.

4.2. Applications for membership shall be lodged in writing with the Chief Executive and shall be accompanied by the prescribed entrance fee and subscription in each case.

4.3. Applications for membership shall be considered by the Executive Committee, within six months of receipt thereof by the Chief Executive. Any subscription paid shall be refunded to the applicant in the event of rejection of the application.

4.4. If admission to membership is refused by the Executive Committee, the applicant concerned shall be notified by the Chief Executive and shall have the right of appeal to the next General Meeting of the Association. The Appeal shall be lodged in writing with the Chief Executive at least 14 days before the date of the next General Meeting. The General Meeting shall have the power to confirm or overturn the decision of the Executive Committee.

4.5. Every member shall notify the Chief Executive, in writing, of his contact details, and changes thereof within fourteen days of the date on which the change took place.

4.6. A member who has resigned or been expelled from the Association may be readmitted as a member on such conditions as the Executive Committee may determine.

4.7. Only one representative of a firm, partnership or company which is a member of the Association shall be entitled to vote on its behalf at meetings of the Association or in ballots conducted by the Association.

5. SUBSCRIPTIONS

5.1. An entrance fee not exceeding R5 000 shall be paid to the Association on application for membership. The Executive Committee may, in extraordinary circumstances, exempt an employer from the payment of an entrance fee.

5.2. A subscription not exceeding R10 000 per annum per individual employer in the case of associated membership, or, in the case where subscriptions are calculated on the basis of the number of employees employed by the employer, not exceeding R6 000 per employee per annum, shall be

X2

DEPARTMENT OF EMPLOYMENT AND LABOUR

NO. R. 1876 **15 February 2022**

CODE OF PRACTICE: MANAGING EXPOSURE TO SARS-COV-2 IN THE WORKPLACE, 2022

Notice is hereby given that the Code of Good Practice: Managing Exposure to SARS-CoV-2 in the Workplace set out in the Schedule is issued by the Minister of Employment and Labour after consideration by NEDLAC in terms of section 203(2A) of the Labour Relations Act, 1995 (Act No. 66 of 1995) to take effect on the date of the lapsing of the Declaration of a National State of Disaster declared under GN313 of 15 March 2020 and extended in terms of section 27(2) of the Disaster Management Act, 2002 (Act No.57 of 2002).

MR TW NXESI, MP
MINISTER OF EMPLOYMENT AND LABOUR
DATE: 15 MARCH 2022

SCHEDULE

CODE OF PRACTICE: MANAGING EXPOSURE TO SARS-COV-2 IN THE WORKPLACE, 2022

ARRANGEMENT OF CODE OF PRACTICE

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CHAPTER 1
INTRODUCTORY PROVISIONS

1. Introduction

(1) A national state of disaster to counter the magnitude and severity of the COVID-19 outbreak was declared on 15 March 2020 in terms of section 27(1) of the Disaster Management Act, 2002 (Act No.57 of 2002).

(2) On 29 April 2020 the Minister responsible for Cooperative Government and Traditional Affairs published Regulations in terms of section 27(2) of that Act, which Regulations were amended to respond to the changing circumstances of the pandemic. Those Regulations included measures that applied to the workplace.

(3) On 29 April 2020 the Minister responsible for Employment and Labour published a Direction on Occupational Health and Safety Measures in Certain Workplaces in terms of regulation 4(10) of those Regulations, which amended and consolidated to respond to the changing circumstances of the pandemic.

(4) On the expiry of the declaration of the national state of disaster, the Regulations and the Direction will cease to have legal effect. Because there remains an ongoing need to prevent and mitigate the risks associated with SARS-CoV-2 exposure in the workplace, it is necessary to incorporate those provisions in the Regulations and the Direction relevant to preventing and mitigating those risks.

(5) The Occupational Health and Safety Act, 1993 (Act No. 85 of 1993)(OHSA), read with its regulations and incorporated standards, requires the employer to provide and maintain as far as is reasonably practicable a working environment that is safe and without risks to the health of workers and to take such steps as may be reasonably practicable to limit or mitigate the hazard or potential hazard.

(6) The OHSA further requires employers, to ensure, as far as is reasonably practicable, that all persons who may be directly affected by their activities

(such as customers, clients or contractors and their workers who enter their workplace or come into contact with their employees) are not exposed to hazards to their health or safety. This obligation also applies to self-employed persons (for example, plumbers or electricians) whose working activities bring them into contact with members of the public.

(7) For the purposes of OHSA in the workplaces to which this Code applies, the identifiable hazard relating to COVID-19 faced by workers, is the virus infecting a worker, the virus transmission by an infected person to other workers in the workplace and the risk of serious illness or death if infected. In workplaces to which the public has access, the hazard includes transmission of the virus by members of the public. Each situation requires special measures to be implemented by employers in order to prevent infection and transmission of the virus or mitigate the risk of serious illness or death.

(8) The Regulations for Hazardous Biological Agents, 2022 (HBA Regulations)[1] list coronavirus as a listed hazardous biological agent, classed as Group 3. It therefore places legal responsibilities on employers in respect of employers to limit the exposure and mitigate the risks of infection by SARS-CoV-2.

(9) The primary obligation is to conduct a risk assessment in terms of regulation 6 to determine the risk of exposure and the control measures to limit infection, transmission and mitigate the risk of serious illness or death on the part of employees and other persons who may be directly affected by the activities of the workplace.

2. Purpose of this Code

(1) A purpose of this Code is to guide employers and employees in managing exposure to SARS-CoV-2 in the workplace by providing guidance to employers and employees in -

[1] [link]

(a) conducting or updating a risk assessment in terms of the OHSA and the HBA in respect of SARS-CoV-2 exposure;

(b) developing a plan to limit infection, transmission and mitigate the risks of serious illness or death on the basis of that risk assessment;

(c) implementing the plan;

(d) managing absence from work due to infection, isolation and adverse effects of vaccination;

(e) seeking to accommodate employees who refuse or fail to vaccinate against SARS-CoV-2 .

(2) Another purpose of this Code is to require any person interpreting an employment law to take this Code into account in respect of any matter arising from its application. This includes employees, trade unions, employers, employers' organisations, inspectors, conciliators, arbitrators and judges.

(3) To the extent that this Code advances an interpretation of the law, that interpretation is the policy of the Minister and the Department and should be applied unless that interpretation is reversed by a decision of the courts.

(4) Apart from those provisions of this Code that reproduce the obligations contained in the employment laws, the Code is intentionally general because workplaces and their requirements differ. Accordingly departures from the non-obligatory provisions of this Code may be justified in appropriate circumstances. Any employer or employee who departs from them must demonstrate justifiable reasons for doing so.

3. Interpretation

(1) In this Code, a word or expression bears the meaning assigned to it in the Basic Conditions of Employment Act, 1997 (Act No. 75 of 1997) or the Occupational Health and Safety Act, 1993 (Act No. 85 of 1993) and unless the context otherwise indicates –

"adverse event following immunisation" means an adverse event caused by a SARS-CoV-2 vaccination and includes adverse events following immunization as categorised by the WHO[2];

"BCEA" means the Basic Conditions of Employment Act, 1997 (Act No. 75 of 1997);

"COVID-19" means Coronavirus Disease 2019 as a result of infection of the SARS-CoV-2 virus;

"Department" means the Department of Employment and Labour;

"EVDS" means the Government's Electronic Vaccination Data System[3];

"HBA Regulations" means Regulations for Hazardous Biological Agents promulgated in terms of section 43 of OHSA in GN R..... of 2022;

"inspector" means a person –

(a) designated as an inspector in terms of section 28 of OHSA;

(b) with the approval of the Minister responsible for Transport, a railway safety inspector appointed in terms of section 32 of the National Railway Safety Regulator Act, 2002 (Act No. 16 of 2002) in respect of a "network" and a "railway operation" as those terms are defined in that Act;

(c) law enforcement officers appointed with public health responsibilities by a local authority authorised in terms of section 17(1);

"LRA" means the Labour Relations Act, 1995 (Act No. 66 of 1995);

"NDOH" means the National Department of Health;

"OHSA" means the Occupational Health and Safety Act, 1993 (Act No. 85 of 1993);

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[2] https://vaccine-safety-training.org/adverse-events-classification.html
[3] https://www.gov.za/covid-19/vaccine/evds

"PPE" means personal protective equipment contemplated in section 11;

"SAHPRA" means the South African Health Products Regulatory Authority in terms of the Medicines and Related Substances Act, 1965 (No.1 of 1965);

"**SARS-CoV-2**" means severe acute respiratory syndrome coronavirus 2, the virus responsible for causing the coronavirus disease 2019 (COVID-19). SARS-CoV-2 has undergone numerous changes over time, resulting in the emergence of several variants. Some of these, that are likely to cause severe disease are referred to as "variants of concern" and include the Beta, Delta and Omicron variants.

"reasonable accommodation" means any modification or adjustment to a job or to the working environment that will allow an employee who fails or refuses to be vaccinated to remain in employment and incorporates the relevant portions of the Code of Good Practice: Employment of People with Disabilities published in terms of the Employment Equity Act, 1999 (Act 97 of 1999);

"vaccination certificate" means a certificate issued by the EVDS or a COVID-19 Vaccination Record Card issued by the NDOH or any other digital certificate issued outside the Republic and recognised by the NDOH;

"vaccinated" means fully vaccinated with vaccines and includes an additional dose or booster and **"vaccination"** has the same meaning;

"vaccines" means the COVID-19 vaccines and boosters that have been scientifically evaluated and recommended by the WHO and registered or authorised by SAHPRA to be effective in preventing severe disease and death;

"**virus**" means the SARS-CoV-2 virus;

"worker" means any person who works in an employer's workplace including an employee of the employer or contractor, a self-employed person or volunteer[4]; and

"workplace" means any premises of an employer or place where a person performs work.

4. Application

(1) Subject to subsections (2) and (3), this Code applies to workplaces except those excluded from the OHSA in terms of section 1(3) of the OHSA.[5]

(2) Despite the exclusion of mines, mining areas and works referred to in subsection (1), section 18 of this Code applies to these workplaces.

(3) Subject to the employer's obligations under the OHSA to conduct a risk assessment, employers with less than 20 employees need only apply the measures set out in section 13.

CHAPTER 2
RISK ASSESSMENT AND PLAN

5. Risk assessment and plan

(1) Every employer must-

(a) undertake a risk assessment to give effect to its obligations under the OHSA and the HBA Regulations;

(b) on the basis of the risk assessment develop or amend its existing plan to include-

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[4] The distinction between 'worker' and 'employee' in this Code is used to ensure that all persons who in work in a workplace are protected and to locate the responsibility in respect of certain obligations imposed on the employer in respect of its employees such as an application for illness benefits or worker's compensation.
[5] Section 1(3) of OHSA excludes mines, mining areas or works in terms the Minerals Act, 1991(Act No. 50 of 1991) and ships, boats or cranes in terms of the Merchant Shipping Act, 1951 (Act No. 57 of 1951.

(i) any measures to be implemented in respect of the vaccination of its employees and, taking into account the intervals between vaccinations, the dates by which the employees must be fully vaccinated; and

(ii) any other protective measures contemplated section 6 (1) and (2);

(c) consult on the risk assessment and plan with-

(i) any representative trade union as contemplated by section 14(1) of the LRA; and

(ii) any health and safety committee established in terms of section 19 of the OHSA or, in the absence of such a committee, a health and safety representative designated in terms of section 17(1) of the OHSA or employee representative; and

(d) make that risk assessment and plan available for inspection by the trade union and committee contemplated in paragraph (c) and an inspector.

6. Contents of risk assessment and plan

(1) The risk assessment and plan referred to in section 5 (1)*(b)* must include-

(a) the identification of the employees contemplated in paragraph (i) of that section;

(b) the reporting of symptoms by employees and isolation of employees who are diagnosed with COVID-19 and are symptomatic;

(c) the workplace protective measures required to be taken in terms of the HBA Regulations including personal protective equipment and ventilation;

(d) a procedure to resolve any issue that may arise from the HRA by an employee of the right to refuse to work in the circumstances contemplated in section 15 (1); and

(e) the process by which the obligations under this Code will be complied with.

(2) The risk assessment and plan referred to in section 5 (1)*(b)* may include-

(a) social distancing measures including minimising the number of workers in the workplace through rotation, staggered working hours, shift and remote working arrangements;

(b) PPE measures contemplated in section 11;

(c) personal hygiene measures such as the wearing of facecloth masks, barriers, hand washing, sanitisers and surface disinfectants;

(d) any special measures to mitigate the risk of infection or serious illness or death in respect of individual employees at increased risk such as reducing the numbers in and the duration of occupancy in meeting rooms.

(3) In developing and implementing a plan in terms of subsection (1)*(b)*(i), an employer must comply with section 12.

CHAPTER 3
ADMINISTRATIVE MEASURES

7. Notification of workers

(1) An employer must notify workers on its premises of the contents of this Code and its plan contemplated in section 5(1)(b) and the manner in which it intends to implement it.

(2) It must provide workers with information that raises awareness in any form or manner, including, where reasonably practicable, leaflets and notices placed in conspicuous places in the workplace informing workers of-

(a) the dangers of the virus, the manner of its transmission, the measures to prevent infection or limit transmission such as personal hygiene, social distancing, use of facecloth masks and cough etiquette;

(b) the symptoms associated with COVID-19 as described from time to time by the clinical guidelines published by the National Institute of Communicable Diseases[6];

(c) the nature of vaccines used in the country, the benefits associated with these COVID-19 vaccines, the contra-indications for vaccination and the nature and risk of any serious side effects[7].

8. Symptom reporting by workers

(1) Every employer must take measures –

(a) to determine the vaccination status of their workers;

(b) to require workers to immediately inform their employer if they experience any of the symptoms associated with COVID-19 contemplated in section 7(2)(b).

(2) Subject to subsection (3), if an employee informs their employer that they experience COVID-19-related symptoms, the employer may require the employee to be tested for COVID-19 before permitting the employee to enter the workplace or report for work.

(3) Subsection (2) does not apply to workers who report the presence of COVID-19 symptoms between one to three days after vaccination.

9. Isolation of workers

(1) Workers who have been diagnosed with COVID-19 and are symptomatic must-

(a) inform their employer; and

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[6]https://www.nicd.ac.za/diseases-a-z-index/disease-index-covid-19/covid-19-guidelines/guidelines-for-case-finding-diagnosis-management-and-public-health-response/

[7] See the information supplied in the NIOH site: https://www.nicd.ac.za/covid-19-vaccine-faq/

(b) isolate themselves for the period as recommended by the National Department Health[8], unless a longer period is recommended by a medical practitioner.

(2) In the circumstances contemplated in subsection (1) or section 8(2), an employer must-

(a) place the employee on paid sick leave in terms of section 22 of the BCEA or if the employee's sick leave entitlement under the section is exhausted, make application for an illness benefit in terms of section 20 of the Unemployment Insurance Act, 2001 (Act No. 63 of 2001);

(b) take steps to ensure that the employee is not discriminated against on grounds of having tested positive for SARS-CoV-2 in terms of section 6 of the Employment Equity Act, 55 of 1998; and

(c) if there is evidence that the worker contracted COVID-19 arising out and in the course of employment, lodge a claim for compensation in terms of the Compensation for Occupational Injuries and Diseases Act, 130 of 1993, in accordance with Notice No. 629 published on 22 October 2019.[9]

10. Ventilation

(1) In accordance with its obligation under the OHSA, regulation 5 of the Environmental Regulations for Workplaces[10] and the HBA Regulations, every employer must –

(a) keep the workplace well ventilated by natural or mechanical means to reduce the SARS-CoV-2 viral load;

(b) identify areas in the workplace that are usually occupied and poorly ventilated, and improve ventilation through-

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[8] https://sacoronavirus.co.za/2022/02/18/circular-changes-to-covid-19-quarantine-isolation-and-contact-tracing/
[9] GNR 387 GG 4350 of 23 July 2020.
[10] Environmental Regulations for Workplaces GNR 2281 of 16 October 1987.

(i) natural ventilation including opening doors, windows and vents and where possible cross ventilation in preference to single-sided ventilation;

(ii) ventilation through the use of fans, air conditioners or mechanical ventilation.

(c) where reasonably practicable, have an effective mechanical ventilation system that –

(i) is technically assessed to be functioning effectively and in accordance with the manufacturer's instructions;

(ii) is regularly serviced and maintained by a competent person in particular that ventilation filters are cleaned and replaced in accordance with the manufacturer's instructions;

(iii) supplies fresh air at an adequate ventilation rate;

(iv) does not have ventilation vents that feed-back through open windows;

(v) does not recirculate the air; and

(vi) if appropriate in terms of the Guidelines referred to in paragraph (d), have High Efficiency Particulate Air Filters; and

(d) ensure that ventilation is in accordance with the NDOH Guidelines for ventilation to prevent the spread of SARS-CoV-2 virus.[11]

11. Specific personal protective equipment

Every employer must check regularly on the websites of the National Department of Health[12], National Institute of Communicable Diseases[13] and the National Institute for Occupational Health[14] whether any specialised

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[11] https://www.nioh.ac.za/wp-content/uploads/2021/08/V1.1-Guidelines-for-ventilation-to-prevent-the-spread-of-the-SARS-CoV-2-virus-FINAL.pdf
[12] htt p:// www.health.gov.za/.
[13] https://www.nicd.ac.za/.
[14] http://www.nioh.ac.za/.

PPE for COVID-19 is required or recommended in any guidelines based on the nature of the workplace or the nature of a worker's duties and the associated level of risk.

12. Vaccination of employees

(1) Every employer must in accordance with the measures contemplated in section 5 (1)*(b)*(i)-

(a) notify the employee identified in terms of section 6(1)*(a)* of the obligation to be vaccinated;

(b) counsel the employee on the issues related to vaccines in section 7 (1)*(c)*;

(c) permit the employee, at the employee's request, to consult a health and safety representative, a worker representative or a trade union official;

(d) give administrative support to the employees to register and to access their COVID-19 vaccination certificates on the EVDS Portal for SARS-CoV-2[15]; and

(e) give the employee paid time off to be vaccinated and provide transport for the employee to and from the nearest vaccination site.

(2) In giving effect to this Code, an employer may require its employees to disclose their vaccination status and to produce a vaccination certificate.

(3) Should an employee suffer a vaccine adverse event that renders them unable to work, the employer must –

(a) on receipt of a medical certificate, give the employee paid time off to recover if the employee is no longer entitled to paid sick leave in terms of the BCEA or any applicable collective agreement; or

(b) subject to any regulations in respect of a COVID-19 Vaccine Injury No-Fault Compensation Scheme[16], lodge a claim for compensation in terms

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[15] vaccine.enroll.health.gov.za/#/
[16] GNR 376 *GG* 44485 of 22 April 2021.

of the Compensation for Occupational Injuries and Diseases Act, 130 of 1993.

(4) If an employee refuses to be vaccinated, the employer must-

(a) counsel the employee and, if requested, allow the employee to seek guidance from a health and safety representative, worker representative or trade union official;

(b) take steps to reasonably accommodate the employee in a position that does not require the employee to be vaccinated.

(5) If an employee produces a medical certificate attesting that an employee has contra-indications for vaccination, the employer may refer the employee for a medical evaluation for confirmation at the employer's expense.

(6) If the employer accepts the medical certificate or the employee is referred to medical evaluation and that evaluation confirms that the employee has contra-indications for vaccination, it must accommodate the employee in a position that does not require the employee to be vaccinated.

13. Small businesses

Employers with 20 employees or less must -

(a) undertake a risk assessment of the workplace and take any reasonably practicable measure that may mitigate the risk of infection and transmission of the virus or the risk to employees of serious illness or death contemplated in section 6(2) and (3);

(b) comply with section 12 if a measure contemplated in section 5 (1)*(b)*(i) is introduced;

(c) if an employee has COVID-19 related symptoms –

(i) refuse to allow the employee to enter the workplace;

(ii) comply with section 9;

(d) to the extent reasonably practicable, ventilate occupied closed spaces in the workplace in accordance with section 10(1).

14. Worker obligations

In addition to the obligations of employees under the OHSA and the HBA Regulations, every worker is obliged to comply with the employer's plan contemplated in section 5 (1)(b).

15. Refusal to work

(1) An employee may refuse to perform any work if circumstances arise which, with reasonable justification, appear to that employee or to a health and safety representative to pose an imminent and serious risk of their exposure to SARS-CoV-2 virus infection.

(2) An employee who has refused to perform work in terms of subsection (1) must, as soon as is reasonably practicable, notify the employer, either personally or through a health and safety representative, of the refusal and the reason for the refusal.

(3) Every employer that has been notified in terms of this section must –

(a) after consultation with the health and safety committee or, if there is no committee, a health and safety representative, endeavour to resolve any issue that may arise from the exercise of the right in terms of subsection (1);

(b) if the matter cannot be resolved internally, notify an inspector[17] of the issue within 24 hours and advise the employee and all other parties involved in resolving the issue that an inspector has been notified; and

(c) comply with any prohibition issued by an inspector in terms of section 30 of the OHSA.

(4) Subsection (1) applies whether or not the person refusing to work has used or exhausted any other applicable external or internal procedure.

[17] Notification by contacting the relevant provincial inspectorate at the telephone numbers listed in Annexure C or at an address in http://www.labour.gov.za/Contacts/Provincial-offices.

(5) No person may benefit from, or promise any benefit to any person for, not exercising his or her right in terms of subsection (1).

(6) No person may threaten to take any action against a person because that person has exercised or intends to exercise the right in terms of subsection (1).

(7) No employee may be dismissed, disciplined, prejudiced or harassed for refusing to perform any work as contemplated in subsection (1).

(8) If there is a dispute as to whether subsection (7) has been contravened, the employee may refer the dispute to the Commission for Conciliation, Mediation and Arbitration or an accredited bargaining council for conciliation and arbitration in accordance with the procedures contained in section 191 of the Labour Relations Act, 66 of 1995.

(9) If the arbitrator, appointed as contemplated in subsection (8), finds that the employer has contravened subsection (7), the arbitrator may make any appropriate order contemplated in section 193, read with 194(3) or (4) of the Labour Relations Act, 1995.

16. No deduction from employee's remuneration

No employer may make any deduction from an employee's remuneration or require or permit an employee to make any payment to the employer or any other person, in respect of anything which the employer is obliged to provide or to do in terms of this Code.

17. Monitoring and enforcing this Code

(1) To the extent that this Code gives effect to the OSHA, the Minister responsible for Employment and Labour may authorise local authorities to perform certain inspectorate functions in terms of section 42(3) of the OSHA.

(2) In so far as any contravention of this Code constitutes a contravention of an obligation or prohibition under the OHSA or HBA Regulations-

(a) an inspector may perform any of the functions in section 29 of the OHSA and exercise any of the powers listed in section 30 of the OHSA to monitor compliance with this Code;

(b) the offences and penalties provided for in section 38 of the OHSA apply.

(3) An inspector may, for the purpose of promoting, monitoring and enforcing compliance with the OHSA and the HBA Regulations, advise employees and employers of their rights and obligations in accordance with section 64 of the BCEA.

18. Limited application to mines, mining areas and works

If an employer of a mine, mining area or works requires its employees to be vaccinated as part of its mandatory code of practice prepared and implemented in terms of the Guideline for the Compilation of a Mandatory Code of Practice for the Prevention, Mitigation and Management of COVID-19 Outbreak[18], section 12(4), (5) and (6) applies to any employee who refuses or fails to be vaccinated.

19. Amendment of footnotes

The Minister may from time to time amend and publish the footnotes to this Code online on the Department's website without issuing an amended Code in order to update the links and references that the footnotes contain.

[18] GN 701 of 6 August 2021 *GG* 44947.

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Minister Thulas Nxesi issues code of practice on management of SARS-CoV-2 exposure in workplace

15 Mar 2022

Thulas Nxesi, Minister of Employment and Labour, issues Code of Practice: Management exposure to SARS-CoV-2 in the workplace

Thulas Nxesi, Minister of Employment and Labour, issued a code of practice on the management of SARS-CoV-2 exposure in the workplace today, 15 March 2022, under government notice number 46043.

The notice was issued following consideration by NEDLAC in accordance with section 203 (2A) of the Labour Relations Act, 1995 (Act No. 66 of 1995), to take effect on the date of the lapse of the Declaration of a National State of Disaster declared under GN313 on 15 March 2020, and was extended in accordance with section 27(2) of the Disaster Management Act (Act No 57 of 2002).

The code's purpose is to assist employers and employees in managing SARS-CoV-2 exposure in the workplace by guiding employers and employees in conducting or updating a risk assessment in accordance with the Occupational Health and Safety Act, 1993 (Act No 85 of 1993) (OHASA) and Hazardous Biological Agents, 2022 (HBA Regulations) in respect of SARS-CoV-2 exposure, developing a plan to limit infection, transmission, and mitigate the risks of serious illness.

In due course, the Minister will issue Occupational Health and Safety (OHS) regulations to supplement the Code.

The Department has identified an error in the published gazette that incorrectly states the issue date as 15 February 2022; this error is being reviewed and will be corrected. The correct issue date is 15 March 2022.

This gazette is available free online at www.gpwonline.co.za/ www.labour.gov.za

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Issued by: Department of Employment and Labour
More from: Department of Employment and Labour
More on: CoronavirusLabour

RELATED INFORMATION

Disaster Management Act: Code of Practice: Managing exposure to SARS-COV-2 in the workplace [PDF]

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GOVERNMENT NOTICES • GOEWERMENTSKENNISGEWINGS

DEPARTMENT OF CO-OPERATIVE GOVERNANCE

NO. R. 1988 **4 April 2022**

TERMINATION OF THE NATIONAL STATE OF DISASTER (COVID-19)

DISASTER MANAGEMENT ACT, 2002: (ACT NO. 57 OF 2002):

On 15 March 2020, I declared a national state of disaster (Covid-19) in terms of my powers under section 27(1)(*a*) of the Disaster Management Act, 2002 (the Act). This was extended in terms of section 27(5)(*c*) of the Act at one-month intervals to 15 April 2022.

I have, together with Cabinet, considered the current situation and the steps taken to augment existing legislation and contingency arrangements, and have decided to terminate the national state of disaster.

In determining precisely when each of the Regulations and Directions should be repealed, I have given consideration to, inter alia, the need for post-disaster recovery and rehabilitation, including the need to anticipate future disaster risk, reduce exposure, improve resilience, mitigate the effects of the disaster, create circumstances that will reduce the risks of a similar disaster and deal with the destructive and other effects of the disaster.

Therefore, I, Dr Nkosazana Dlamini Zuma, Minister of Cooperative Governance and Traditional Affairs, designated under section 3 of the Act, in terms of section 27(5)(*b*) of the Act hereby terminate the national state of disaster which I declared on 15 March 2020 as published in Government Gazette No. 43096 in Notice No.313 and which, in terms of section 27(5)(*c*) of the Act, I extended at one month intervals to 15 April 2022 and published in Government Gazette No. 46042 in Notice R. 1875.

(1) All regulations and directions made in terms of section 27(2) of the Act pursuant to the declaration of the national state of disaster to deal with Covid-19, are hereby repealed with immediate effect, save for the following:

(*a*) Regulation 67;

(*b*) Regulations 69;

(*c*) Regulations 75;

(*d*) Directions, as amended, issued in terms of Regulation 4(5) and (10), which provide for Social Relief of Distress Grant;

(*e*) Directions, as amended, issued in terms of Regulation 4(7)(*b*), which provide for the extension of the validity period of a learner's license, driving licence card, licence disc, professional driving permit and registration of a motor vehicle; and

(*f*) The Regulations in Chapter 8 and the Directions in terms thereof, which provide for the COVID-19 Vaccine Injury No-Fault Compensation Scheme.

(2) The Regulations and Directions referred to in subsection (1)(*a*) to (*e*) shall -

(*a*) not cease to operate or cease to be of force and effect due to the termination of the national state of disaster; and

(*b*) continue to operate and be of force and effect for a period of one month from today, whereupon they will automatically lapse.

(3) The Regulations and Directions referred to subsection (1)(*f*) shall -

(*a*) not cease to operate or cease to be of force and effect due to the termination of the national state of disaster; and

(*b*) continue to operate and be in force until terminated in terms of Regulation 100 of Chapter 8.

NC Zuma

DR NKOSAZANA DLAMINI ZUMA, MP

MINISTER OF COOPERATIVE GOVERNANCE AND TRADITIONAL AFFAIRS

DATE: 04.04.2022.

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GOVERNMENT NOTICES • GOEWERMENTSKENNISGEWINGS

DEPARTMENT OF EMPLOYMENT AND LABOUR

NO. R. 1887 **16 March 2022**

OCCUPATIONAL HEALTH AND SAFETY ACT, 1993

HAZARDOUS BIOLOGICAL AGENTS REGULATIONS, 20...

The Minister of Employment and Labour has, under section 43 of the Occupational Health and Safety Act, 1993 (Act No. 85 of 1993), after consultation with the Advisory Council for Occupational Health and Safety, made the regulations in the Schedule.

MR TW NXESI MP
MINISTER OF EMPLOYMENT AND LABOUR
DATE: 03/03/2022

SCHEDULE

Definitions

1. In these Regulations any word or expression to which a meaning has been assigned in the Act has the meaning so assigned and, unless the context indicates otherwise—

"biohazard" means any potential laboratory source of harm caused by biological agents, microbial by-products or metabolites;

"biological agent" means any microorganism, microbial by-products or metabolites, cell or organic material with plant, animal or human origin, including any which have been genetically modified;

"competent person" means a person who has, in respect of the work or task to be performed, the required knowledge, training, experience and, where applicable, qualifications specific to HBAs;

"control measures" means measures that remove, prevent or reduce the exposure of persons to HBAs at the workplace;

"decontamination" means the procedure that eliminates or reduces biological agents to a level that does not cause harm with respect to the transmission of infection or other adverse effects;

"disinfect" means to render non-viable virtually all recognised pathogenic microorganisms, but not necessarily all microbial forms;

"Facilities Regulations" means the Facilities Regulations, 2004, as published in Government Notice No. R. 924 of 3 August 2004;

"HBA" means a hazardous biological agent which may cause an infection, allergy or toxicity or otherwise create a risk to human health, subdivided into the following groups:

(a) Group 1 HBA, an HBA that is unlikely to cause human disease;

(b) Group 2 HBA, an HBA that may cause human disease and be a hazard to exposed persons, which is unlikely to spread to the

community and for which effective prophylaxis and treatment is usually available;

(c) Group 3 HBA, an HBA that may cause severe human disease, which presents a serious hazard to exposed persons and which may present a risk of spreading to the community, but for which effective prophylaxis and treatment is available; and

(d) Group 4 HBA, an HBA that cause severe human disease and is a serious hazard to exposed persons and which may present a high risk of spreading to the community, but for which no effective prophylaxis and treatment is available;

"laboratory" means a room or part of a building equipped for experimentation, research, testing or manufacture of drugs or chemicals or which may manipulate microbiological agents;

"microorganism" means a microbiological entity, cellular or non-cellular, capable of replication or transferring genetic material;

"monitoring" means the planning and carrying out of a measurement programme and the recording of the results thereof;

"respiratory protective equipment" means a device which is worn over at least the mouth and nose to prevent the inhalation of airborne HBAs, and which conforms to a standard, acceptable to the chief inspector;

"safety equipment" means equipment which is designed to prevent exposure to HBAs;

"standard precautions" means a synthesis of the major features of Universal Precautions (UP) and Body Substances Isolation (BSI) and applies to all persons coming into contact with potentially infected persons, animals or animal products and potentially contaminated blood and other fluids in the workplace and—

(a) apply to—

(i) all blood;

(ii) all body fluids, secretions and excretions, except sweat, regardless of whether they contain visible blood or not;

(iii) non-intact skin;

(iv) mucous membrane; and

(v) tissues; and

(b) are designed to reduce the risk of transmission of HBAs from both recognised and unrecognised sources of exposure to HBAs in the workplace;

"the Act" means the Occupational Health and Safety Act, 1993 (Act No. 85 of 1993);

"Universal Precautions" means an approach to infection control to treat all human blood and certain human body fluids as if they were known to be infectious for HIV, HBV and other blood-borne pathogens;

"ventilation" means the process of supplying or removing air to or from an indoor space for the purpose of controlling air contaminants level, humidity or temperature within the space; and

"verification" means the process of establishing the accuracy or validity of something.

Scope of application

2. (1) Subject to sub regulation (2), these Regulations apply to every employer or self-employed person at a workplace where—

(a) an HBA is produced, processed, used, handled, stored or transported; or

(b) exposure to an HBA may occur.

(2) Regulations 8, 14, 15, 16 and 17 do not apply to an employer or self-employed person at a workplace where the exposure is restricted to a Group 1 HBA.

Classification of biological agents

3. (1) Biological agents must be assigned a classification of Group 1, Group 2, Group 3 or Group 4 according to hazard and categories of contaminant by the chief inspector in consultation with the HBAs health and safety technical committee.

(2) Where a biological agent has not been assigned a classification as contemplated in subregulation (1), the employer or self-employed person must provisionally classify that biological agent in accordance with subregulation (3), having

regard to the nature of the biological agent and the properties of which he or she may reasonably be expected to be aware and must without delay notify the chief inspector of the provisional classification and the reason therefor. The chief inspector may make a decision based on the recommendation of the HBAs technical committee.

(3) When provisionally classifying a biological agent, the employer or self-employed person must conduct a risk assessment and assign that biological agent to one of the groups and if there is doubt according to its level of risk of infection as to which of two alternative groups would be most appropriate, the biological agent must be assigned to the higher of the two.

Information, instruction and training

4. (1) An employer who undertakes work which exposes an employee to HBAs must inform the relevant health and safety representative or the health and safety committee established for that workplace of the—

(a) intention to conduct—

(i) a risk assessment contemplated in regulation 6;

(ii) exposure monitoring contemplated in regulation 7;

(iii) medical surveillance contemplated in regulation 8; and

(iv) training contemplated in subregulation (2);

(b) documented outcomes of the—

(i) risk assessment contemplated in regulation 6;

(ii) exposure monitoring contemplated in regulation 7; and

(iii) medical surveillance contemplated in regulation 8.

(2) An employer must ensure that any employee at risk of being exposed or exposing others to HBAs is comprehensively informed, instructed and trained in both the practical aspects and theoretical knowledge with regard to—

(a) the contents and scope of these Regulations;

(b) the potential risks to health caused by the exposure;

(c) the measures to be taken by the employer to protect an employee against any risk of being exposed;

(d) the importance of good housekeeping at the workplace and personal hygiene requirements;

(e) the precautions to be taken by an employee to protect him or her against the health risks associated with the exposure, including the wearing and use of protective clothing and respiratory protective equipment;

(f) the necessity, correct use, maintenance and potential limitation of safety equipment, facilities and engineering control measures provided;

(g) the necessity of risk-based medical surveillance;

(h) the safe working procedures regarding the use, handling, storage, labelling, and disposal of HBAs at the workplace; and

(i) the procedures to be followed in the event of exposure, spillage, leakage, accidental release, injury or any similar emergency situation, and decontaminating or disinfecting contaminated areas.

(3) The employer must ensure that the information, instruction and training referred to in subregulation (1) are provided before an employee is potentially exposed to HBAs.

(4) The employer must conduct refresher training annually or at intervals that may be recommended by the health and safety committee or the health and safety representative.

(5) An employer or self-employed person must give instructions in writing of the procedures contemplated in subregulation (1)*(a)* to the drivers of vehicles carrying HBAs.

(6) Every employer or self-employed person must ensure that he or she or any person who in any manner assist him or her in the carrying out or conducting of the business duties has the necessary information and has undergone instruction and training in order for him or her to identify potential risks and the precautions that should be taken.

Duties of persons who might be exposed to HBAs

5. (1) Any person who is or might be exposed to HBAs must obey any lawful instruction given by or on behalf of the employer or a self-employed person regarding—

(a) the prevention of an uncontrolled release of an HBA;

(b) the adherence to instructions regarding environmental and health practices, personal hygiene and good housekeeping;

(c) the appropriate use of personal protective equipment and clothing as prescribed by these Regulations and the documented risk assessment;

(d) the appropriate wearing of personal samplers, when necessary, to measure personal exposure to airborne HBAs;

(e) the disposal of materials containing HBAs and the disinfection and decontamination of any workplace contaminated by an HBA;

(f) the reporting during normal working hours for such medical examination or tests as contemplated in regulation 8(1); and

(g) information, instruction and training as contemplated in regulation 4.

(2) Any person must immediately report to the employer, the health and safety representative or self-employed person any possible exposure to an HBA at the workplace.

Risk assessment for HBAs

6. (1) A self-employed person must conduct and document the risk assessment to determine if any person could be exposed to an HBA.

(2) An employer must—

(a) conduct and document the risk assessment to determine if any person could be exposed to an HBA; and

(b) ensure that the HBA risk assessment contemplated in paragraph *(a)* is conducted by a competent person.

(3) When conducting the risk assessment, as contemplated in subregulation (1) and (2), the employer or self-employed person must take into account, as a minimum, the following matters:

(a) The nature of the HBA and the possible route of exposure;

(b) where the HBA might be present and in what form it is likely to be;

(c) the nature of the work and work processes;

(d) current control measures in place, effectiveness of control measures and any reasonable deterioration in, or failure thereof; and

(e) what effects the HBA can have on an employee, including pregnant, immunocompromised and vulnerable employees.

(4) An employer or a self-employed person must conduct the risk assessment on the basis of all available information, including—

(a) classification of the HBA into the relevant risk group according to its level of risk of infection as contained in Annexure A;

(b) recommendations from the manufacturer, supplier or a competent person regarding additional control measures necessary in order to protect the health of persons against such agents as a result of their work;

(c) information on diseases that may be contracted as a result of the activities at the workplace;

(d) potential allergenic, infectious or toxic effects that may result from the activities at the workplace; and

(e) knowledge of diseases from which employees might be suffering and which may be aggravated by conditions at the workplace.

(5) An employer must, in terms of the risk assessment–

(a) consider the recommendations identified in the risk assessment; and

(b) develop a documented action plan for the implementation of the recommendations.

(6) An employer must review the assessment required by subregulation (1)—

(a) at intervals not exceeding 24 months;

(b) forthwith, if—

(i) the previous assessment is no longer valid;

(ii) there has been a change in a process involving an HBA;

(iii) there has been a change in the methods, plant or machinery, procedures in the use, handling, control or processing of an HBA;

(iv) an incident occurs involving an HBA; or

(vi) medical surveillance reveals an adverse health effect, where an HBA is identified as a contributing factor.

(7) The employer must ensure that all employees, the relevant health and safety representative and health and safety committee are informed of the results of the risk assessment, who may comment thereon.

Exposure monitoring of HBAs

7. (1) An employer must establish and maintain an exposure monitoring programme at the workplace which is representative of the employees' exposure to HBAs.

(2) The exposure monitoring programme must be—

(a) in accordance with a validated procedure, sufficiently sensitive and of proven effectiveness;

(b) conducted by a competent person;

(c) conducted at intervals determined in the risk assessment but not exceeding 24 months; and

(d) conducted when any change occurs which may affect the exposure.

(3) An employer must, in terms of exposure monitoring—

(a) consider the recommendations identified in the exposure monitoring report; and

(b) develop a documented action plan for the implementation of the recommendations.

Medical surveillance

8. (1) An employer must establish and maintain a documented system of medical surveillance of employees, which is overseen by an occupational health practitioner, if—

(a) the results of the HBA risk assessment contemplated in regulation 6 indicate that an employee is at risk of exposure to HBAs;

(b) the exposure of the employee to the HBA is hazardous to his or her health and is such that—

(i) an identifiable disease or adverse effect to his or her health may be related to the exposure;

(ii) there is a reasonable likelihood that the disease or effect may occur under the particular conditions of his or her work; and

(iii) there are techniques such as preclinical biomarkers, where appropriate, for detecting sensitisation to allergens or an inflammatory response associated with exposure to diagnose indications of the disease or the effect as far as is reasonably practicable; or

(c) an occupational health practitioner recommends that the relevant employee should be under medical surveillance, in which case the employer may call upon an occupational health practitioner to confirm the appropriateness of such recommendation.

(2) In order to comply with the provisions of subregulation (1), the employer must, after in-depth counselling and education, ensure that the medical surveillance consists of—

(a) an initial health evaluation, which should be carried out by an occupational health practitioner immediately before or within 14 days after a person commences employment where risk of exposure exists, which comprises—

(i) an evaluation of the employee's medical and occupational history;

(ii) a physical examination; and

(iii) any biological tests and other appropriate medical tests or any other essential examination that in the opinion of the occupational health practitioner is desirable in order to enable the practitioner to do a proper evaluation;

(b) periodic medical examinations and tests which should be carried out by an occupational health practitioner at intervals specified by him or her but not exceeding 24 months and which consists of—

(i) a physical examination; and

(ii) any biological tests and other appropriate medical tests or any other essential examination that in the opinion of the occupational health practitioner is desirable in order to enable the practitioner to do a proper evaluation;

(c) exit medical examinations and tests which should be carried out by an occupational health practitioner and which consists of—

(i) a physical examination; and

(ii) any biological tests and other appropriate medical tests or any other essential examination that in the opinion of the occupational health practitioner is desirable in order to enable the practitioner to do a proper evaluation.

(3) All tests and examinations as contemplated in subregulation (2) must be conducted according to a written medical protocol following current best practice, national or international guidelines.

(4) All occupational health practitioners must submit to the employer for approval a written protocol for procedures to be followed when dealing with abnormal results.

Records

9. (1) An employer must—

(a) keep records of all training, exposure assessments, exposure monitoring reports and medical surveillance reports required by regulations 4, 6, 7 and 8 respectively;

(b) make the records contemplated in paragraph *(a)*, excluding personal medical records, available for inspection by an inspector, a health and safety representative or a health and safety committee;

(c) make the records contemplated in regulation 8(2)*(b)* available to any person subject to the formal written consent of the employee concerned;

(d) keep all records of risk assessments, medical surveillance and exposure monitoring reports for a minimum period of 40 years;

(e) keep all records of the examinations and tests carried out in terms of regulation 12*(c)* and of any repairs resulting from the investigations and tests for a minimum period of five years;

(f) keep all records of training given to an employee in terms of regulation 4 for as long as the employee remains employed at that particular workplace; and

(g) if the employer or self-employed person ceases activities, hand over all the records to the relevant Chief Director: Provincial Operations.

(2) A self-employed person must keep records of all risk assessments for a minimum period of 40 years, and if the self-employed person ceases activities, all those records must be handed over to the relevant Chief Director: Provincial Operations.

Prevention and control of exposure to HBAs

10. (1) A self-employed person must ensure that the risk of exposure of persons to HBAs is reduced through biological containment and where this is not reasonably practicable, control the exposure to as low as possible.

(2) An employer must ensure that the risk of exposure of persons to HBAs is reduced through biological containment and medical fitness restrictions in the workplace or, where this is not reasonably practicable, control the exposure to as low as possible.

(3) The employer or self-employed person must ensure that the standard precautions are implemented to reduce the risk of transmission of HBAs in a workplace, which may include—

(a) hand hygiene;

(b) gloves;

(c) face or eye protection;

(d) protective clothing;

(e) respiratory protective equipment; and

(f) other relevant process safety equipment.

(4) Where reasonably practicable, the employer or self-employed person must control the exposure to an HBA in the workplace by—

(a) implementing measurers identified in the documented risk assessment;

(b) limiting the amount of HBAs used which might contaminate the workplace to the minimum quantity required for the task;

(c) limiting the number of employees;

(d) limiting the duration of exposure of employees;

(e) introducing measures for the control of exposure, which must include any combination of the following contamination control measures:

(i) Separation of different infectious processes from each other and from persons;

(ii) barrier isolation of a process or agent;

(iii) local exhaust ventilation;

(iv) general ventilation;

(v) air and surface disinfection;

(iv) positive static air pressure differential from infectious process to human occupied zones;

(vii) suppression of emissions of an airborne HBA;

(viii) access control to prevent unauthorised access; and

(ix) immediately accessible emergency personal or environmental disinfection;

(f) introducing appropriate work procedures that employees must follow where HBAs are handled, used and processed that could give rise to the exposure of an employee to HBAs, and such procedures must include documented instructions to ensure—

(i) the safe handling, use and disposal of HBAs;

(ii) the proper use and maintenance of machinery, installations, equipment, tools and local exhaust and general ventilation systems;

(iii) the regular cleaning of machinery and work areas with vacuum cleaners fitted with air filters with an arrestance of not less than 99,95%;

(iv) a system is in place that identifies the need for early corrective action from changes to work procedures and practices; and

(v) the decontamination and disinfection of the affected workplace;

(g) making available effective vaccines for those employees who are not immune to the biological agent to which they are exposed or are liable to be exposed;

(h) specifying procedures for taking, handling and processing samples that might contain HBAs; and

(i) displaying the biohazard sign as depicted in Annexure B and other relevant information.

Personal protective equipment and facilities

11. (1) If it is not reasonably practicable to ensure that the exposure of an employee is controlled as contemplated in regulation 10, the employer must, in the case of—

(a) airborne, ingestion and contact transmission, provide the employee with suitable protective equipment and protective clothing; and

(b) HBAs that can be absorbed through the skin, provide the employee with suitable impermeable personal protective clothing.

(2) Where respiratory protective equipment is provided, the employer must ensure that—

(a) the relevant safety equipment is capable of preventing the exposure to the HBA concerned;

(b) the relevant safety equipment is correctly selected, fitted and properly used;

(c) information, instructions, training and supervision which would be necessary with regard to the use and disposal of the safety equipment are known to the employees; and

(d) the reusable safety equipment is kept in hygienic condition and efficient working order.

(3) An employer must, as far as is reasonably practicable—

(a) not issue personal protective equipment which has been used to an employee unless it is capable of being decontaminated and disinfected prior to use;

(b) provide separate containers or storage facilities for protective equipment and protective clothing when not in use; and

(c) take steps to ensure that all protective equipment and protective clothing not in use are stored in a demarcated area with proper access control.

(4) An employer must, as far as is reasonably practicable, ensure that all contaminated reusable personal protective clothing issued is cleaned and handled in accordance with the following procedures:

(a) Where such clothing is cleaned on the premises of the employer, care must be taken to prevent contamination during handling, transporting and cleaning;

(b) where clothing is sent off the premises to a contractor for cleaning purposes, the contractor must place the clothing in impermeable, tightly sealed colour coded containers and such containers must be clearly identified with a biohazard label as depicted in Annexure B;

(c) where clothing from facilities handling HBA Risk Group 3 and Risk Group 4 agents is sent off the premises for any purposes, it must first be decontaminated; and

(d) it must be ensured that the contractor as contemplated in subregulation (4)*(b)* is fully informed of the requirements of these

Regulations and the precautions to be taken regarding the handling of contaminated clothing.

(5) Subject to the provisions of the Facilities Regulations, an employer must, where reasonably practicable, provide employees using personal protective equipment and clothing as contemplated in subregulation (1) with—

(a) adequate washing facilities which are readily accessible and located in an area where the facilities will not become contaminated, in order to enable the employees to meet the standard of personal hygiene consistent with the adequate control of exposure, and to avoid the spread of HBAs;

(b) two separate lockers labelled "protective clothing" and "general clothing" respectively, and ensure that the general and protective clothing is kept separately in the lockers concerned; and

(c) separate "clean" and "contaminated" change rooms if the employer uses or processes HBAs to the extent that the HBA could endanger the health of persons outside the workplace.

Maintenance and verification of control measures, plant machinery and facilities

12. The employer must ensure that—

(a) documented risk-based protocols are developed, maintained by a competent person and made available at the workplace for all control measures, plant machinery and facilities provided in terms of regulations 6, 10 and 11, which include—

(i) performance parameters and minimum acceptance criteria;

(ii) performance verification methodology and intervals;

(iii) routine maintenance requirements, specifications and intervals;

(iv) relevant standards, regulations and manufacturer's requirements; and

(v) minimum competency and training required to perform verification and maintenance activities;

(b) all control measures, plant machinery and facilities provided in terms of regulations 6, 10 and 11 are maintained in good working

order and in accordance with the protocols referred to in paragraph *(a)*;

(c) thorough examination and tests of control measures, plant machinery and facilities provided in terms of regulations 6, 10 and 11 are carried out in accordance with the protocols referred to in paragraph *(a)*, but at intervals not exceeding 24 months;

(d) outcomes of tests of control measures are documented and available for inspection; and

(e) the protocols referred to in paragraph *(a)* comply with any applicable guideline issued by the chief inspector.

Prohibitions

13. (1) No person may—

(a) use compressed air to remove HBAs from any surface or person;

(b) eat, drink, smoke, keep food or beverages or apply cosmetics where an HBA is handled or require or permit any other person to eat, drink, smoke, keep food or beverages or apply cosmetics in such a workplace; or

(c) leave a controlled area without prior removal of potentially contaminated protective clothing and safety equipment.

(2) An employer or self-employed person must cause a notice and/or signage to be posted at a conspicuous place containing the provisions of subregulation (1).

Labelling, packaging, transporting and storage

14. An employer or self-employed person must, as far as is reasonably practicable, take steps to ensure that—

(a) all HBAs under his or her control in storage, transit or being distributed are properly contained and controlled to prevent the spread of contamination from the workplace;

(b) the colour coded containers in which HBAs are transported are clearly marked with a biohazard sign as depicted in Annexure B and other relevant warning signs that identify the contents;

(c) transport of HBAs is performed with due consideration of Chapter VIII of the National Road Traffic Act, 1996 (Act No. 93 of 1996), and the International Air Transport Association (IATA) Infectious Substances Shipping Regulations; and

(d) authorisations for the transport and storage of biological agents as required by the National Health Act, 2003 (Act No. 61 of 2003): Regulations Relating to the Registration of Microbiological Laboratories and the Acquisition, Importation, Handling, Maintenance and Supply of Human Pathogens, 2012, as published in Government Notice No. R. 178 of 2 March 2012, the Non-Proliferation of Weapons of Mass Destruction Act, 1993 (Act No. 87 of 1993), the Animal Health Act, 2002 (Act No. 7 of 2002), and the Genetically Modified Organisms Act, 1997 (Act No. 15 of 1997), are adhered to where applicable.

Disposal of HBAs

15. An employer or self-employed person must—

(a) lay down written procedures for appropriate decontamination and disinfection;

(b) implement written procedures enabling infectious waste to be handled and disposed of without risk;

(c) provide sufficient hazardous waste containers for disposal of used personal protective equipment;

(d) ensure that all fixtures, plant and machinery including vehicles, reusable containers and covers which have been in contact with HBA waste are disinfected and decontaminated after use in such a manner that it does not cause a hazard inside or outside the workplace concerned;

(e) ensure that all employees involved in the collection, transport and disposal of HBA waste and who may be exposed to that waste are provided with suitable personal protective equipment;

(f) ensure that if the services of a waste disposal contractor are used, a provision is incorporated into the contract stating that the

contractor must comply with the provisions of these Regulations; and

(g) ensure that HBA waste that can cause exposure is treated and disposed of only on sites specifically designated and authorised for this purpose in terms of the National Environmental Management: Waste Act, 2008 (Act No. 59 of 2008), in such a manner that it does not cause a hazard inside or outside the site concerned.

HBAs health and safety technical committee

16. (1) The chief inspector must establish an HBAs health and safety technical committee which must consist of—

(a) a person who is to be the chairperson;

(b) two persons designated by the chief inspector from the employees of the Department of Employment and Labour;

(c) three persons designated by employers' organisations to represent employers;

(d) three persons designated by employees' organisations representing the federation of unions;

(e) one representative of each of the professional bodies recognised by the chief inspector; and

(f) one person from the field of HBAs representing a higher educational institution.

(2) The chief inspector may—

(a) authorise the HBAs health and safety technical committee to co-opt persons who have specialised knowledge of the matters dealt with by the HBAs health and safety technical committee; and

(b) appoint members of the HBAs health and safety technical committee for a period that he or she may determine at the time of appointment.

(3) The HBAs health and safety technical committee must—

(a) advise the chief inspector on HBA related matters, including but not limited to codes, standards and training requirements;

(b) make recommendations and submit reports to the chief inspector regarding any matter to which these Regulations relate;

(c) advise the chief inspector regarding any matter referred to the HBAs health and safety technical committee by the chief inspector;

(d) perform any other function for the administration of a provision of these Regulations that may be requested by the chief inspector; and

(e) conduct its work in accordance with the instructions and rules of conduct framed by the chief inspector.

Offenses and penalties

17. Any person who contravenes or fails to comply with any provision of regulations 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14 or 15 will be guilty of an offence and liable on conviction to a fine or to imprisonment for a period not exceeding 12 months and, in the case of a continuous offence, to an additional fine of R200 for each day on which the offence continues or additional imprisonment of one day for each day on which the offence continues: Provided that the period of such additional imprisonment shall in no case exceed 90 days.

Withdrawal of regulations

18. The Regulations for Hazardous Biological Substances, 2001, published as Government Notice No. R. 1390 of 27 December 2001, are hereby withdrawn.

Short title

19. These Regulations are called the Regulations for Hazardous Biological Agents.

ANNEXURE A

CATEGORISATION OF BIOLOGICAL AGENTS ACCORDING TO RISK GROUP

INTRODUCTION

1. The attached list must be read in conjunction with the Hazardous Biological Agents Regulations, and in particular regulation 3.

2. Biological agents listed are categorised into the following risk groups on the basis of their ability to cause human disease by infection, allergy and/or toxicity, potential to cause epidemics or pandemics, endemicity in South Africa and availability of curative or prophylactic treatment:

   Risk group 1: a microorganism known not to or unlikely to cause human disease.
   Risk group 2: a pathogen that may cause human disease but unlikely to pose serious hazard to laboratory workers, the community and the environment. Specific treatment or vaccines may be available to manage or prevent infection with these pathogens.
   Risk group 3: a pathogen that may cause serious human disease but does not typically spread from human to human. Treatment and vaccines may be available to manage or prevent infection with these pathogens.
   Risk group 4: a pathogen that may cause serious human disease and may be readily transmissible from human to human. Specific treatment and preventative measures are typically not available for the diseases caused by these pathogens.

3. In allocating biological agents to a risk group, account is not taken of effects on those whose susceptibility may be affected for one or other reason such as pre-existing disease, medication, compromised immunity, pregnancy or breastfeeding. Workplace specific risk to such workers should be considered per risk assessment as in regulation 6.

4. Biological agents that have not been classified for inclusion in groups 2 to 4 of the list are not implicitly classified as Group 1. All viruses that have been

isolated in humans and that have not been assessed and allocated to a group in the list are to be classified in group 2 as a minimum, except where there is evidence that they are unlikely to cause disease in humans.

5. If more than one species of any particular agent is known to be pathogenic to humans, the most prominent of these is generally named, together with the wider reference "species" (spp.) to indicate the fact that the other species of the same genus may be hazardous. If a whole genus is mentioned in this way, it is implicit that species and strains that are non-pathogenic to humans are excluded.

6. When a strain is attenuated or has lost known virulence genes, then the containment required by the classification of its parent strain need not necessarily apply, subject to risk assessment as per regulation 6, for example, when such strain is used as a product or as part of a product for prophylactic or therapeutic purposes (see point 2).

7. The requirements as to containment consequent upon the classification of parasites apply only to stages in the life cycle of the parasite in which it is liable to be infectious, allergic or toxic to humans.

8. The list also gives a separate indication where biological agents are capable of causing allergic or toxic reactions, and where a registered vaccine is available for use in the Republic of South Africa.

   The indications are identified by the following notations:

   - A: possible allergic effects;
   - T: toxin production; and
   - V: vaccine available.

9. The selection of control measures for biological agents should take into account the fact that there are no exposure limits for them. Their ability to replicate and to infect, cause allergic or toxic effects, at very low doses, means that exposure may have to be reduced to levels that are diminishingly low.

   For each activity the first consideration should be whether it can be carried out in a way that involves exposure to a less harmful biological agent. This may be

practicable, for example, in teaching and some types of research. If there is more than one way of carrying out the activity, then the method carrying the least risk should be chosen.

If the least harmful alternative still involves exposure or potential exposure to a biological agent, or the nature of the activity is such that there is no choice, and it is not reasonably practicable to prevent exposure by some other means, then exposure should be adequately controlled.

10. Agents with reduced virulence may be used at a lower than normal level of containment if the alteration has effectively changed their classification.

A biological agent that falls or is treated as falling into hazard Group 1 may be a Group 3 genetically modified organism because of environmental risks associated with it or because, though now unlikely to cause human disease, it is derived by genetic modification from a pathogenic parental organism. In the latter case, the selection of containment measures appropriate to the agent's reduced virulence and corresponding group may be permitted. Where there is a mismatch, as in the case of a genetically modified organism or biological agent that is non-hazardous to humans but environmentally harmful, the more stringent requirements should be followed.

Where the rules set out lead to a particular containment level for an activity, all the measures appropriate to that level should normally be used. Some selection may be done, however, to suit individual circumstances, provided that by doing so the risk is not increased.

Regulation 11 sets out additional requirements in respect of personal protective equipment used to protect employees against biological agents. The objective of these requirements is to prevent the equipment itself from acting as the means by which agents are transmitted, and they should be followed accordingly.

Where workers are exposed to biological agents, the information and instruction given to them, if applicable, should be set down in the form of written instructions, outlining procedures to be followed after a serious incident

involving the handling of a biological agents as well as the procedure for handling any Group 4 agent.

If the nature of the workplace and the activity are such that employees may need instant access to this information, or where a reduction in risk may be expected by having the information conspicuously displayed in the workplace then it should also be set out on notices displayed in the workplace.

Table 1:

Prescribed risk groups for parasitic agents (in alphabetic order)

BIOLOGICAL AGENT	RISK GROUP	BIOLOGICAL AGENT	RISK GROUP
Helminths			
Ancylostoma spp.	2	*Hymenolepis* spp.	2
Angiostrongylus spp.	2	*Loa* spp.	2
Anisakis spp.	2	*Mansonella* spp.	2
Ascaris lumbricoides	2 (A)	*Metagonimus* spp.	2
Brugia spp.	2	*Necator* spp.	2
Capillaria spp.	2	*Onchocerca* spp.	2
Clonorchis spp.	2	*Opisthorchis* spp.	2
Contraceacum osculatum	2	*Paragonimus* spp.	2
Dicrocoelium dendriticum	2	*Pseudoterranova decipiens*	2
Dipetalonema spp.	2	*Schistosoma* spp.	2
Diphyllobothrium spp.	2	*Strongyloides* spp.	2
Dipylidium caninum	2	*Taenia* spp.	2
Dracunculus medinesis	2	*Taenia solium*	3
Echinococcus spp.	3	*Ternidens deminutus*	2
Enterobius spp.	2	*Toxocara* spp.	2
Fasciola gigantica	2	*Trichinella* spp.	2
Fasciola hepatica	2	*Trichostrongylus* spp.	2
Fasciolopsis buski	2	*Trichuris trichiura*	2
Heterophyes spp.	2	*Wuchereria* spp.	2
Protozoa			
Acanthamoeba spp.	2	*Leishmania* spp.	2
Babesia spp.	2	*Leishmania brasiliensis*	3
Balantidium spp.	2	*Leishmania donovani*	3
Blastocytis hominis	2	*Linguatula* spp.	2
Coccidia spp.	2	*Macracanthorhynchus* spp.	2
Cochliomyia hominivorax	2	*Microsporidia* spp.	2
Cryptosporidium spp.	2	*Naegleria fowleri*	3
Cyclospora spp.	2	*Naegleria* spp. (other than *fowleri*)	2
Cysticerus cellulosae	2	*Oesophagostomum dentalum*	2
Dientamoeba fragilis	2	*Plasmodium* spp. (human and simian)	2
Encephalitozoon spp.	2	*Plasmodium falciparum*	3
Entamoeba spp.	2	*Pneumocystis carinii*	2
Enterocytozoon bieneusi	2	*Sarcocystis* spp.	2

Giardia spp.	2	*Toxoplasma* spp.	2
Gnathostoma spinigerum	2	*Trichomonas vaginalis*	2
Gongylonema pulchrum	2	*Trypanosoma* spp.	2
Haemonchus contortus	2	*Trypanosoma brucei gambiense*	3
Isospora spp.	2	*Trypanosoma brucei rhodesiense*	3

Table 2:

Prescribed risk groups for fungal agents (in alphabetic order)

BIOLOGICAL AGENT	RISK GROUP	BIOLOGICAL AGENT	RISK GROUP
Absidia spp.	2	*Lacazia loboi*	3
Acremonium spp.	2	*Leptosphaeria* spp.	2
Ajellomyces spp.	3	*Lichtheimia corymbifera*	2
Arthroderma spp.	2	*Madurella* spp.	2
Aspergillus spp.	2	*Malassezia* spp.	2
Basidiobolus haptosporus	2	*Microsporum* spp.	2
Blastomyces dermatitidis	3	*Mucor* spp.	2
Candida spp.	2	*Neotestudina rosatii*	2
Cladophialophora bantiana	3	*Paecilomyces variottii*	2
Other *Cladophialophora* spp	2	*Paracoccidioides brazilensis*	3
Cladosporium spp.	3	*Penicillium marneffei*	3
Coccidioides and Paracoccidioides spp.	3	*Pseudallescheria boydii*	2
Cryptococcus spp.	2	*Rhinocladiella mackenziei*	3
Dermatophilus congolensis	2	*Rhizomucor pusillus*	2
Emmonsia crescens	2	*Rhizopus* spp.	2
Emmonsia parva	2	*Saksenaea vasiformis*	2
Epidermophyton spp.	2	*Scedosporium* spp.	2
Exophiala spp.	2	*Scopulariopsis brevicaulis*	2
Filobasidiella spp.	2	*Sporothrix schenckii*	2
Fonsecaea spp.	2	*Stachybotrys chartarum*	2
Fusarium spp.	2	Trichophyton spp.	2
Geotrichum spp.	2	Trichosporon spp.	2
Histoplasma spp.	3	*Xylohypha bantiana*	3

Table 3:

Prescribed risk groups for bacteria, rickettsiae and mycoplasmas (in alphabetic order)

BIOLOGICAL AGENT	RISK GROUP	BIOLOGICAL AGENT	RISK GROUP
Abiotrophia spp.	2	*Kingella* spp.	2
Achromobacter spp.	2	*Klebsiella* spp.	2
Acidaminococcus fermentans	2	*Kluyvera* spp.	2
Acidovorax spp.	2	*Koserella trabulsii*	2
Acinetobacter spp.	2	*Lactobacillus* spp.	2
Actinobacillus spp.	2	*Lactococcus garvieae*	2
Actinobaculum schaalii	2	*Leclercia adecarboxylata*	2
Actinomadura spp.	2	*Legionella* spp.	2

BIOLOGICAL AGENT	RISK GROUP	BIOLOGICAL AGENT	RISK GROUP
Actinomyces spp.	2	*Leptospira* spp.	2
Aeromonas spp.	2	*Levinea malonatica*	2
Afipia spp.	2	*Liberobacter* spp.	2
Alcaligenes spp.	2	*Listeria* spp.	2
Alloiococcus otitis	2	*Mannheimia* spp.	2
Allomonas enterica	2	*Megasphaera elsdenii*	2
Alteromonas haloplanktis	2	*Melissococcus pluton*	2
Amycolata autotrophica	2	*Microvirgula aerodenitrificans*	2
Anaerobiospirillum spp.	2	*Mima polymorpha*	2
Anaerorhabdus furcosus	2	*Mitsuokella multacida*	2
Anaplasma spp. R41	2	*Mobiluncus* spp.	2
Arachnia spp.	2	*Moraxella* spp.	2
Arcanobacterium spp.	2	*Morganella morganii*	2
Arcobacter butzleri	2	*Morococcus cerebrosus*	2
Arizona spp.	2	*Mycobacterium africanum*	3 (V)
Arsenophonus nasoniae	2	*Mycobacterium avium/intracellulare*	2
Arthrobacter spp.	2	*Mycobacterium bovis*	3 (V)
Atopobium spp.	2	*Mycobacterium bovis* (BCG strain)	2
Bacillus anthracis	3 (V)	*Mycobacterium chelonae*	2
Bacillus cereus	2	*Mycobacterium fortuitum*	2
Bacteroides spp.	2	*Mycobacterium kansasii*	2
Balneatrix alpica	2	*Mycobacterium leprae*	3 (V)
Bartonella spp. (except *B. bacilliformis*)	2	*Mycobacterium malmoense*	3
Bartonella pertussis	2 (V)	*Mycobacterium marinum*	2
Bartonella bacilliformis	3	*Mycobacterium microti*	3*
Beneckea spp.	2	*Mycobacterium paratuberculosis*	2
Bergeyella zoohelcum	2	*Mycobacterium scrofulaceum*	2
Bifidobacterium dentium	2	*Mycobacterium simiae*	2
Bilophila wadsworthia	2	*Mycobacterium szulgai*	3
Bordetella spp.	2	*Mycobacterium tuberculosis*	3 (V)
Borrelia spp.	2	*Mycobacterium ulcerans*	3*
Brachyspira spp.	2	*Mycobacterium xenopi*	2
Brevibacterium spp.	2	*Mycoplasma* spp.	2
Brevinema andersonii	2	*Myroides* spp.	2
Brevundimonas diminuta	2	*Neisserria* spp.	2
Brucella spp.	3	*Neisseria meningitidis*	2 (V)
Burkholderia spp. (except *B. mallei*)	2	*Nocardia* spp.	2
Burkholderia mallei	3	*Nocardiopsis dassonvillei*	2
Burkholderia pseudomallei	3	*Ochrobactrum anthropi*	2
Calymmatobacterium granulomatis	2	*Oligella* spp.	2
Campylobacter spp.	2	*Orientia tsutsugamushi*	3
Capnocytophaga spp.	2	*Pasteurella* spp.	2
Cardiobacterium hominis	2	*Peptococcus* spp.	2
Catonella morbi	2	*Peptostreptococcus* spp.	2
Cedecea spp.	2	*Photobacterium* spp.	2
Cellulomonas hominis	2	*Plesiomonas shigelloides*	2
Centipeda periodontii	2	*Porphyromonas* spp.	2

BIOLOGICAL AGENT	RISK GROUP	BIOLOGICAL AGENT	RISK GROUP
Chlamydia spp. (except *C. psittaci*, avian strains)	2	*Prevotella* spp.	2
Chlamydia psittaci (avian strains)	3	*Propionibacterium* spp.	2
Chlamydophila spp.	2	*Proteus* spp.	2
Chromobacterium violaceum	2	*Providencia* spp.	2
Chryseobacterium spp.	2	*Pseudomonas* spp.	2
Citrobacter spp.	2	*Pseudoramibacter alactolyticus*	2
Clavibacter michiganensis	2	*Psychrobacter phenylpyruvicus*	2
Clostridium spp.	2	*Rhodococcus* spp.	2
Clostridium botulinum	2 (T, V)	*Rickettsia* spp.	3
Clostridium tetani	2 (T, V)	*Riemerella columbina*	2
Clostridium diphtheria	2 (T, V)	*Rochalimaea* spp.	2
Comamonas terrigena	2	*Saccharopolyspora rectivirgula*	2
Corynebacterium spp.	2 (T, V)	*Salmonella* spp.	2
Coxiella burnetii	3	*Salmonella* Paratyphi A	3*
Curtobacterium flaccumfaciens	2	*Salmonella* Paratyphi B/java	3*
Dermatophilus congolensis	2	*Salmonella* Paratyphi C/Choleraesuis	3*
Dialister pneumosintes	2	*Salmonella typhi*	3* (V)
Dichelobacter nodosus	2	*Selenomonas* spp.	2
Dolosigranulum pigrum	2	*Serpulina* spp.	2
Edwardsiella spp.	2	*Serratia* spp.	2
Ehrlichia spp.	2	*Serratia liquefaciens*	2
Ehrlichia sennetsu	3	*Shewanella algae*	2
Eikenella corrodens	2	*Shigella* spp.	2
Empedobacter brevis	2	*Shigella dysenteriae* (type 1)	3 (T)
Enterobacter spp.	2	*Sphaerophorus necrophorus*	2
Enterococcus spp.	2	*Sphingobacterium* spp.	2
Eperythrozoon spp.	2	*Sphingomonas* spp.	2
Erwinia spp.	2	*Spiroplasma mirum*	2
Erysipelothrix spp.	2	*Sporichthya brevicatena*	2
Escherichia spp.	2	*Staphylococcus* spp.	2
Escherichia coli verocytotoxigenic strains (e.g. O157:H7)	3 (T)	*Staphylococcus aureus*	2 (T)
Eubacterium spp.	2	*Stenotrophomonas* spp.	2
Ewingella americana	2	*Streptobacillus* spp.	2
Facklamia hominis	2	*Streptococcus* spp.	2
Faenia rectivirgula	2	*Streptomyces somaliensis*	2
Falcivibrio spp.	2	*Sutterella wadsworthensis*	2
Elizabethkingia meningoseptica	2	*Suttonella indologenes*	2
Flexibacter spp.	2	*Tatlockia* spp.	2
Fluoribacter spp.	2	*Tatumella ptyseos*	2
Francisella tularensis	3 (Type A, V)	*Tissierella praeacuta*	2
Fusobacterium spp.	2	*Treponema* spp.	2
Gardnerella vaginalis	2	*Tsukamurella* spp.	2
Gemella spp.	2	*Turicella otitidis*	2
Globicatella sanguinis	2	*Ureaplasma* spp.	2

BIOLOGICAL AGENT	RISK GROUP	BIOLOGICAL AGENT	RISK GROUP
Gordonia spp.	2	*Veillonella parvula*	2
Haemophilus spp.	2	*Vibrio* spp.	2
Hafnia alvei	2	*Vibrio cholera*	2 (T, V)
Hallella seregens	2	*Waddlia chondrophila*	2
Helcococcus spp.	2	Yersinia spp. (except *Y. pestis*)	2
Helicobacter spp.	2	*Yersinia pestis*	3 (V)
Johnsonella ignava	2		
Jonesia denitrificans	2		

** Routine diagnosis of M. tuberculosis infection based on microscopy, PCR and primary culture can be conducted under level 2 conditions, whereas culture manipulation for identification, drug-susceptibility testing and line probe assays on cultured isolates should be conducted under level 3 conditions.*

Table 4:

Prescribed risk groups for viruses. This list pertains primarily to human pathogens, but also includes other viruses that may be frequently used in experimentation (for example baculovirus for protein expression) or veterinary pathogens that will be likely processed in medical laboratories (for example BSL 4 agents) (*unassigned species refer to species not specifically listed here) (in alphabetic order per family).

BIOLOGICAL AGENT	RISK GROUP	BIOLOGICAL AGENT	RISK GROUP
Adenoviridae (human, all types)	2	Lymphocytic choriomeningitis (non-neurotropic)	2
Alphaviridae:		Machupo	4
Chikungunya	3	Mopeia	3
Middelburg	3	Mobala	3
Ndumu	3	Oliveros	4
O'nyong-nyong	3	Paraná	4
Semliki forest	3	Pichinde	4
Shuni	3	Tamiami	4
Sindbis	3	Sabiá	4
Ross river	3	Putative *arenaviridae* species or unassigned species	4
Eastern equine encephalitis	4	*Astroviridae*	
Western equine encephalitis	4	*Baculoviridae*	2
Venezuelan equine encephalitis	4	*Birnaviridae*	2
Putative *alphaviridae* species or unassigned species*	3	*Bornaviridae*	2
Arenaviridae (mammarenaviruses):		*Bunyaviridae:*	
Amapari	2	Bunyamwera	3
Guanarito	4	California encephalitis	3
Flexal	3	Crimean-Congo Haemorrhagic fever	3**

BIOLOGICAL AGENT	RISK GROUP	BIOLOGICAL AGENT	RISK GROUP
Ippy	3	Hanta (all species)	4
Junín	4	Nairobi sheep disease	3
Lassa	4	Rift Valley fever	3
Lujo	4	Sandfly fever	3
Lymphocytic choriomeningitis (neurotropic)	3	St Floris	3
		Putative *bunyaviridae* species or unassigned species (not Hanta)	3
Caliciviridae:		Japanese encephalitis	3
Hepatitis E	2	Kadam	3
Noro	2	Koutango	3
Sapo	2	Kokobera	3
Putative *caliciviridae* species or unassigned species	2	Kumlinge	4
Coronaviridae (human):	2	Kyasanur Forest	4
Severe acute respiratory syndrome-2 (SARS CoV2)	3*(V)		
Severe acute respiratory syndrome (SARS) (or SARS-like) Middle Eastern respiratory syndrome (MERS) (or MERS-like)	3	Langat	4
Putative *coronaviridae* species or unassigned species	2	Louping ill	4
Filoviridae:	Murray Valley encephalitis	3	
Ebola	4	Ntaya	3
Marburg	4	Negishi	3
Putative *filoviridae* species or unassigned species	4	San Perlita	3
Flaviviridae:	Spondweni	3	
Absettarov	4	Omsk	4
Bagaza	3	Uganda S	3
Banzi	3	Usutu	3
Bouboui	3	Powassan	3
Central European encephalitis	4	Rocio	3
Dengue	3	Russian spring-summer encephalitis	4
Hanzalova	4	St Louis encephalitis	3
Hepatitis C	2	Tick-borne encephalitis	4
Hepatitis G	3	Wesselsbron	3
Hypr	4	West Nile (including Kunjin)	3
Israel turkey meningoencephalitis	4	Yellow fever, wild type Vaccine strain	3(V) 2
Zika	3	Human metapneumo	2
Putative *flaviviridae* species or unassigned species	3	Hendra	4
Hepadnaviridae:		Measles	2 (V)
Hepatitis B	2 (V)	Menangle	2
Hepatitis D	2	Mumps	2 (V)

BIOLOGICAL AGENT	RISK GROUP	BIOLOGICAL AGENT	RISK GROUP
Herpesviridae:		Nipah	4
Cytomegalo	2	Parainfluenza	2
Epstein-Barr	2	Respiratory syncytial	2
Herpes simplex	2	Rinderpest	4
Herpes 6-8	2	Sendai	2
Herpes simiae (Herpes B)	4	*Parvoviridae:*	
Varicella-zoster	2 (V)	Parvovirus (Human B19)	2
Human B-lymphotropic	2	*Picornaviridae:*	
Pseudorabies	4	Acute haemorrhagic conjunctivitis	2
Putative *herpesviridae* species or unassigned species	2	Coxsackie	2
Orthomyxoviridae:		Echo	2
Influenza (human)	2 (V)	Entero	2
Avian influenza	3	Encephalomyocarditis	2
Dhori	3	Hepatitis A	2 (V)
Tick-borne orthomyxo	2	Polio (Type 1, 3) (Type 2)	2 (V) 3
Thogoto	3	*Poxviridae:*	2
Papovaviridae:		Buffalopox	2
JC/BK	2	Camelpox	2
Papilloma	2 (V)	Cowpox/Milker's nodule virus	2
Polyoma	2	Elephantpox	2
Simian virus 40 (SV40)	2	Horsepox	2
Paramyxoviridae:		Goatpox	2
Avian paramyxo	2		

BIOLOGICAL AGENT	RISK GROUP
Molluscum contagiosum	2
Monkeypox	4
Orf	2
Rabbitpox	2
Variola (minor and major)	4
Pseudopox	2
Yatapox (Tana- and Yabapox)	3
Reoviridae:	
Bluetongue	2
Colti	2
Orbi (including Colorado tick fever)	3
Reo	2
Rota	2 (V)
Putative *reoviridae* species or unassigned species	3
Retroviridae:	
Human immunodeficiency	3*
Human T-cell lymphotropic	3
Simian Immunodeficiency	3

BIOLOGICAL AGENT	RISK GROUP
Rhabdoviridae:	
Bovine ephemeral fever	3
Rabies	2 (V)
Rabies related (including new, unassigned species)	3
Vesicular stomatitis	3
Putative *rhabdoviridae* species or unassigned species	3
Togaviridae:	
See alphaviruses	
Rubella	2 (V)

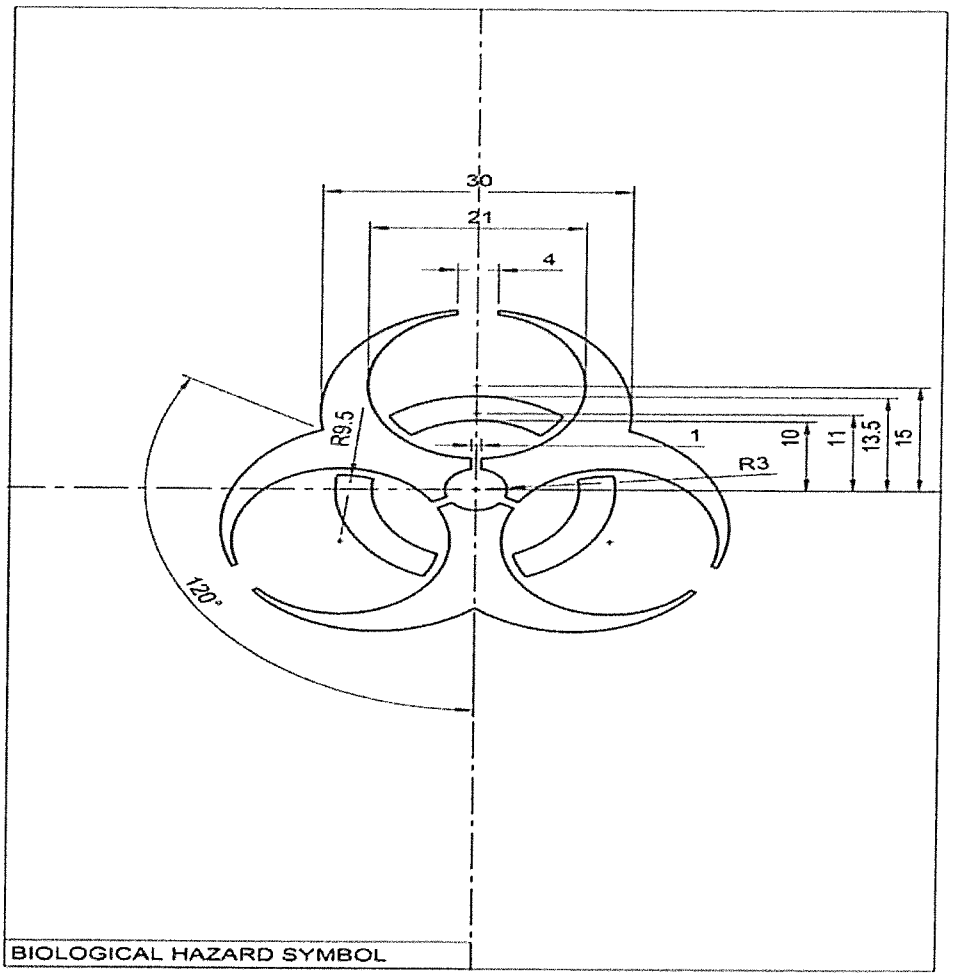
** Biosafety level 2 conditions are applicable to clinical specimens and non-culture procedures. Biosafety level 3 conditions are required for all culture procedures.*

*** Biosafety level 3 conditions are applicable to clinical specimens and non-culture procedures. Biosafety level 4 conditions are required for all culture procedures.*

ANNEXURE B

[Regulations 10(2)*(f)*, 11(4)*(b)* and 14*(b)*]

BIOHAZARD SIGN



BIOLOGICAL HAZARD SYMBOL

Explanatory notes to the Regulations for Hazardous Biological Agents

The purpose of this document is to provide guidance to all employers and employees who are responsible for or concerned with the control and prevention of hazardous biological agent risks in the workplace.

This guide does not replace the Hazardous Biological Agents Regulations of 2021. It is intended to give practical insight into the applications of the Regulations. It should always be read in conjunction with the HBA regulations and the Occupational Health and Safety Act of 1993.

Wearing and use of protective clothing and respiratory protective equipment.

1. Where the HBA exposure cannot be prevented by other means, individual protection measures including PPE must be used. Workers have to be provided with appropriate protective clothing or other appropriate special clothing (ref: Directive 2000/54/EC of 18 September 2000 of the European Parliament on the protection of workers from risks related to exposure to biological agents at work). According to standard EN 14126, protective clothing against biological hazards is classified in accordance with leak tightness and is recognised by the suffix B, e.g. type 3-B.
2. In the selection of the protective clothing, one should note that the efficacy offered by the protection. The larger the number of the protection class, the better is the clothing for that specific property.
3. The user has to be able to perform all the movements, assume the working positions he or she will have when performing the work, and be able to use the working tools. In order to ease the work load, the clothing should be selected so that its donning and removal are easy. The removal has to be straightforward also since different kind of emergencies may arise, and the clothing may need to be taken off quickly. A poor fit of the clothing may result in reduced efficacy of the clothing.
4. If other PPE are needed together with the protective clothing, the efficacy of the entire PPE has to be ensured. Special care has to be taken to ensure that the wearer, who has to wear hearing protection will be protected and be able to communicate and hear warning signals. Wearer trials are needed to ensure the usability of the protective clothing. An evaluation of the maintainability of the clothing is also needed before the selection. The purchase of protective clothing should always be based on a risk assessment.
5. User training must include donning and removal of the protective clothing. Also, pre-use checks (e.g. checking for defects in ensemble assembly, garment and components, accessory, interface (closure, zippers), sufficiency of ventilation rate (gas-tight clothing)), safe work methods and monitoring the clothing while in use. The training should be carried out under realistic conditions and with actual equipment following the same procedures as in the real work task. In user training, the final check of size, fit, and compatibility must be investigated.

6. Decontamination permits the reuse of the types of protective clothing and equipment that are reusable. It can be made through physical or chemical methods to inactivate the contaminant or by using combination of these techniques. The decontamination procedure should not put other people or the environment at risk or damage the PPE. The effectiveness of decontamination should be checked e.g. visually searching for signs of discolorations, swelling, corrosive effects, stiffness or degradation of the material. Single use clothing is used when the contamination cannot be effectively removed from the clothing. Single use clothing is commonly used against microbiological agents.
7. The storage must be arranged to prevent damage to the protective clothing and equipment. Exposure to sunlight, dust, moisture, chemicals, extreme temperatures and mechanical damages e.g. folding must be prevented. Potentially contaminated protective clothing and equipment must be stored separately from unused protective clothing.
8. Regular inspection is necessary and should include inspection when the protective clothing and equipment is first received, inspection when it is selected for a particular task, inspected after use and previous maintenance. Records must be kept of all inspection procedures containing item identification number, date of inspection, person conducting the inspection, results, and unusual findings.
9. In all repair work, the manufacturer's instruction must be followed or the personal protective clothing and equipment must be sent to repair location authorised by the manufacturer.

The emergency preparedness plan

1. The development of an emergency preparedness plan should be based on all-hazards and assessments of risks, and of the available capacity to manage the priority risks. The objective of an emergency response plan is to provide practical ways to reduce the risk of employee's exposure to the disease in the workplace and to deal with any unforeseen situations. The plan should outline actions that employers and employees must take in the event of an emergency situation to ensure their health and safety. The plan should be communicated to all employees, contractors and suppliers. Everyone must be aware of what they should do – or not do – based on the plan, including their duties and responsibilities.
2. The plan must clearly outline the procedures to be followed in the event of an emergency. Such procedures should include:
    - risk assessment;
    - ways to alert employees;
    - Evacuation;
    - emergency response;
    - designated assembly locations;
    - contact people and their telephone numbers;

- first aid and medical assistance;
- clean-up and business resumption;
- reporting emergencies (reporting exposures, incidents, accidental release);
- employee training;
- exposure control procedures (engineering controls, employee training and workplace practices, personal protective equipment)
- ways of testing the plan (drills).

Duties of persons who might be exposed to HBA

1. In addition to the duties indicated in the regulation 5, employees' must report any deviations in the adherence to control measures put in place by the employer to mitigate exposure of a medical nature. This allows employees exposed to HBA to take responsibility to inform the employer of any challenges experienced with control measures put in place as opposed to employee not adhering to measures or being subjected to ill effects of measures without the employer's knowledge.

Competent person

1. Is a person who has, in respect of the work or task to be performed, the required knowledge, training and experience and, where applicable, qualifications specific to hazardous biological agents: Provided that, where appropriate qualifications and training are registered in terms of the National Qualifications Framework Act, 2008 (Act No. 67 of 2008), Skills Development Act, (Act No 97 of 1998) Chapter 6C as well as the Continuing Education and Training Act 16 of 2006, those qualifications and that training must be regarded as the required qualifications and training; and
2. is familiar with the Act and the applicable regulations made under the Act;
3. In general, for people to be competent in the health and safety aspects of their work, they will have a combination of the following requirements:
    - be qualified because of knowledge, training, and experience to do the assigned work;
    - have knowledge about the hazards and risks associated with the job or task to be performed (e.g., knows what hazards and risks are present);
    - know how to recognize, evaluate and control these hazards and risks (e.g., knows what precautions to take or controls to use/are in place for the different hazards or risks);
    - have the ability to work so that their health and safety and the health and safety of others is not in danger;
    - have knowledge of the laws and regulations that apply to the work being done.
4. The level of competence required will depend on the complexity of the situation and the task involved.

5. In all cases, it is the employer who should be able to justify the basis on which a worker is considered to be "adequately qualified", "suitably trained" or "sufficient experience". It is not possible to provide a general list of the exact knowledge, training and experience required. Every organisation must determine the requirements for each position or task to be done. Frequency of competency assessment will depend on the trends of risk outcomes (e.g. incidents), changes in technology or contraventions by the inspectorate which may indicate a need to increase the level of competency.

Confidentiality in relation to records

1. Confidentiality is the right of an individual to have personal, identifiable medical information kept private.
2. Health records are different to medical records in that they should not contain confidential medical information. Health records and medical records must therefore be kept separate to avoid any breaches of medical confidentiality. Any personal medical information should be kept in confidence and held by the occupational health professional responsible for the health surveillance programme. The doctor or nurse should only provide employers with information on fitness to work and any restrictions that may apply in that respect.
3. Medical records can only be released to third parties, such as the employer, in accordance with the Protection of Personal Information (POPI) act and constitution is also applicable.

Biological containment and medical fitness restrictions

1. Biocontainment is a component of biorisk management. The overall objective of biological containment is to confine a hazardous biological agent, thereby reducing the potential for exposure to workers or other persons, and the likelihood of accidental release to the environment.
2. A medical fitness certificate is a document completed by a qualified occupational health practitioner or an occupational medical practitioner. The employee fitness certificate is to ensure that the employee is fit for the task or job he or she is to perform according to his job specification

Safety equipment (Primary Barriers and Personal Protective Equipment)

1. The primary means of physical containment include the use of containment equipment including safety equipment includes biosafety cabinets (BSCs), personal protective equipment (PPE), enclosed containers, and other controls designed to remove or minimise exposures to hazardous biological materials.

2. Personal protective equipment is specialised clothing or equipment worn by workers to provide another layer of protection while handling hazardous biological agents. PPE may include respirators, gloves, safety glasses, lab coats or gowns, and other protective clothing. Biosafety Cabinets are primary containment devices designed to contain hazardous biological agents.

Facility Design and Construction (Secondary Barriers)

1. The facility design and physical features should provide primary barrier protection from the accidental release of hazardous biological agents outside the facility or to the environment. The design and construction of the facility contribute to the laboratory workers' protection. It also provides a barrier to protect people, animals, and the environment outside of the facility from hazardous biological agents that may be accidentally released from the facility. Small and large animal laboratories require additional design considerations to allow for feeding, housing, handling, and containment. These facilities are defined by Animal Biosafety Levels (ABSL) or Biosafety Level – Agriculture (BSL-Ag).

2. The use of specific containment equipment and procedures is determined through risk assessmentsconducted at individual institutions. Important differences exist between risk assessment criteria for public health and worker protection, and requirements for animal, wildlife, plant, and agricultural containment.

Control measures related to appropriate disinfection

Disinfectants must be appropriate for the relevant biological agents or hazards identified and must be used in accordance with the manufacturer's instructions to ensure adequate contact time. Always refer to the safety data sheets to ensure safe use of the product. The following documents will provide further information:

1. Practical Manual for Implementation of the National Infection Prevention and Control Strategic Framework, NDOH, March 2020.
2. COVID-19 Disease: Infection Prevention and Control Guidelines, NDOH, April 2020

Fit testing of Personal Protective Equipment

1. To ensure that a respirator is effective at reducing risk, it is important to conduct respirator fit testing in order to match the user according to their facial characteristics with the correct size and style of the respirator, especially for those working in high risk environments. Respirator fit testing can be either qualitative or quantitative and it is an important element of a respiratory protection programme. Fit testing forms a key part of achieving the objective filtration of hazardous biological agents in protecting the user.
2. Quantitative fit testing is defined in ANSI Z88.2-1992 as "A fit test that uses an instrument to measure the challenge agent inside and outside the respirator." This procedure is more precise than the qualitative fit test. Qualitative fit testing is defined in ANSI Z88.2-1992 as "a pass/fail test that relies on the subject's response to detect the challenge agent.' Since this test relies on the subjective response of the user, the reproducibility and accuracy may vary.
3. Fit testing should be performed at least once annually for workers who is required to wear a particular respirator per specific respirator brand and size. It is also recommended immediately if the user experiences a weight change of 10kg or more, has significant dental changes, or has reconstructive surgery or a facial disfigurement (scarring).

4. Fit testing should not be confused with a respirator fit check. ANSI Z88.2-1992 defines a fit check as "a test by the user to determine if the respirator is properly sealed to the face." It is recommended that a fit check be performed each time the respirator is donned or adjusted. The fit check is a quick method to determine if the respirator is properly sealed to the face. Under part A.6 of ANSI Z88.2-1992, procedures for conducting a fit check are described. The two most commonly performed methods are the positive and negative pressure tests.
5. The positive pressure check requires the user to cover the exhalation valve (if present in the case of elastomeric filtered respirators suggested in times of extremely constrained supply) of the tight-fitting respirator (placing the palm over the valve is usually sufficient) and exhale. If there is no indication of air escaping, the fit is considered satisfactory. The wearer then inhales. If no leakage is detected, the face piece seal is satisfactory.
6. For valved masks during a negative pressure fit check, the inlet opening of the respirator's cartridges or filters are covered prior to inhalation. Fit checking requires exposing the wearer to a challenge agent (isoamyl acetate, saccharin mist, irritant fume). If the wearer does not detect the challenge agent, the fit check is successful. This method is the only way respirators without valves can be effectively tested.

Reference: NDOH. Policy for the regulation of quality respiratory protective equipment (RPE) supply in healthcare. 2020.

Transport of HBA

In addition to the legislation mentioned in the regulations, the employer shall ensure that transport of biological materials internally or externally is in accordance with the organization's risk assessments. The employer shall address all applicable international, national and local transportation requirements and ensure that a system is in place to maintain appropriate controls on shipping packages and transport containers that contain biological materials in accordance with the organization's risk assessments.

INDICATIONS CONCERNING CONTAINMENT MEASURES AND CONTAINMENT LEVELS

For group 1 biological agents, including life-attenuated vaccines, no physical containment measures are prescribed below. For work with group 1 biological agents the principles of good occupational safety and hygiene should be observed.

Where hazardous biological agents can be transmitted through suspended aerosols over long distances they are classified as airborne spread in the table below. Mechanism of transmission including contact, droplet and vector spread are considered as non-airborne spread below.

	Containment measures	Containment levels ✚ Mandatory for animal containment facilities ► Mandatory for industrial processes ⊙ Mandatory for Suite Laboratories			
		2	3 (HBA Not Airborne Spread)	3 (HBA Airborne Spread)	4
1.	Viable microorganisms should be contained in a system which physically separates the process from the environment (closed system).	►Yes	►Yes	►Yes	►Yes
2.	The workplace is to be separated from other areas of the same building.	No	Yes	Yes	Yes
3.	Exhaust and vent gasses, vapours or air should be treated so as to –	Minimise release	Prevent release	Prevent release	Prevent release
4.	Sample collection from a closed system, addition of materials to a closed system and transfer of viable microorganisms to another closed system, should be performed so as to –	►Minimise release	►Prevent release	►Prevent release	►Prevent release

5.	Bulk culture fluids should not be removed from the closed system unless the viable microorganisms have been –	▶Inactivated by validated means	▶Inactivated by validated chemical or physical means	▶Inactivated by validated chemical or physical means	▶Inactivated by validated chemical or physical means
6.	Equipment Seals should be designed so as to –	Minimise release	Prevent release	Prevent release	Prevent release
7.	Closed and potentially contaminated systems should be located within controlled areas –	Optional	Yes	Yes	Yes, and purpose-built
8.	biohazard signs should be posted (SANS 1186-1);	Yes	Yes	Yes	Yes
9.	personnel should wear protective clothing;	Yes, work clothing	Yes	Yes	Yes, a complete change ⊙ positive pressure protective suits
10.	decontamination and washing facilities should be provided for personnel (e.g. hand and eye wash, safety showers)	Yes	Yes	Yes ⊙ Suite decontaminatio n at containment perimeter	Yes ⊙ Suite decontaminatio n at containment perimeter
11.	personnel should shower before leaving the controlled area;	No	Optional	Optional ✚ Yes	Yes
12.	effluent from sinks and	No	Optional	✚ Yes	Yes

	showers should be collected and inactivated before release;				
13.	the controlled area should be adequately ventilated to minimise air contamination;	Optional	Optional	Yes	Yes
14.	the controlled area should be maintained at an air pressure negative to atmosphere;	No	Optional	Yes	Yes
15.	air supplied the controlled area should be HEPA filtered;	No	Optional	Optional ▶Prevent backflow	Yes
16.	all air extracted from the controlled area should be HEPA filtered;	No	Optional	Yes	Yes (Double HEPA Filtered)
17.	the controlled area should be designed to contain spillage of the entire contents of closed system;	Optional	Yes	Yes	Yes
18.	the controlled area should be sealable to permit fumigation.	No	Optional	Optional ✚ Yes	Yes
19.	Effluent treatment before final discharge.	Inactivated by validated means	Inactivated by validated chemical or physical means	Inactivated by validated chemical or physical means	Inactivated by validated physical means

20.	Access is to be restricted to authorised persons only.	Yes	Yes	Yes, via air-lock	Yes, via air-lock key procedure
21.	The workplace is to be sealable to permit disinfection.	No	Yes	Yes	Yes
22.	Specified disinfection procedure.	Yes	Yes	Yes	Yes
23.	The workplace is to be maintained at an air pressure negative to atmosphere.	No	Yes	Yes	Yes
24.	Efficient vector control, eg rodents and insects.	Recommended ✙ Yes	Recommended ✙ Yes	Yes	Yes
25.	Surfaces impervious to water and easy to clean.	Yes, for bench	Yes, for bench and floor (and walls for animal containment)	Yes	Yes, for bench, floor, walls and ceiling
26.	Surfaces resistant to acids, alkalis, solvents, disinfectants.	Yes, for bench	Yes, for bench and floor (and walls for animal containment)	Yes	Yes, for bench, floor, walls and ceiling
27.	Safe and secure storage of biological agents.	Yes	Yes	Yes	Yes, secure storage
28.	An observation window, or alternative, is to be present, so that occupants can be seen.	No	Yes	Yes	Yes
29.	A laboratory is to contain its own equipment.	No	Yes	Yes, so far as is reasonably practicable	Yes

30.	Infected material, including any animal, is to be handled in a safety cabinet or isolator or other suitable containment.	Yes, where aerosol produced	Yes	Yes, where aerosol produced	Yes
31.	Incinerator for disposal of animal carcases.	Accessible service	Accessible service	Accessible service	Yes, on site

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FDA NEWS RELEASE

Coronavirus (COVID-19) Update: FDA Limits Use of Janssen COVID-19 Vaccine to Certain Individuals

For Immediate Release:

May 05, 2022

Español (/news-events/press-announcements/actualizacion-sobre-el-coronavirus-covid-19-la-fda-limita-el-uso-de-la-vacuna-contra-el-covid-19-de)

Today, the U.S. Food and Drug Administration has limited the authorized use of the Janssen COVID-19 Vaccine to individuals 18 years of age and older for whom other authorized or approved COVID-19 vaccines are not accessible or clinically appropriate, and to individuals 18 years of age and older who elect to receive the Janssen COVID-19 Vaccine because they would otherwise not receive a COVID-19 vaccine.

Key Points:

- After conducting an updated analysis, evaluation and investigation of reported cases, the FDA has determined that the risk of thrombosis with thrombocytopenia syndrome (TTS), a syndrome of rare and potentially life-threatening blood clots in combination with low levels of blood platelets with onset of symptoms approximately one to two weeks following administration of the Janssen COVID-19 Vaccine, warrants limiting the authorized use of the vaccine.
- The FDA has determined that the known and potential benefits of the vaccine for the prevention of COVID-19 outweigh the known and potential risks for individuals 18 years of age and older for whom other authorized or approved COVID-19 vaccines are not accessible or clinically appropriate, and for individuals 18 years of age and older who elect to receive the Janssen COVID-19 Vaccine because they would otherwise not receive a COVID-19 vaccine.
- The Fact Sheet for Healthcare Providers Administering Vaccine (https://www.fda.gov/media/146304/download) now reflects the revision of the authorized use of the Janssen COVID-19 Vaccine and includes a warning statement at the beginning of the fact sheet for prominence which summarizes information on the risk for TTS. Additionally, information on the revision to the authorized use of

the vaccine and updated information on this risk of blood clots with low levels of blood platelets has been added to the Fact Sheet for Recipients and Caregivers (https://www.fda.gov/media/146305/download).

"We recognize that the Janssen COVID-19 Vaccine still has a role in the current pandemic response in the United States and across the global community. Our action reflects our updated analysis of the risk of TTS following administration of this vaccine and limits the use of the vaccine to certain individuals," said Peter Marks, M.D., Ph.D., director of the FDA's Center for Biologics Evaluation and Research. "Today's action demonstrates the robustness of our safety surveillance systems and our commitment to ensuring that science and data guide our decisions. We've been closely monitoring the Janssen COVID-19 Vaccine and occurrence of TTS following its administration and have used updated information from our safety surveillance systems to revise the EUA. The agency will continue to monitor the safety of the Janssen COVID-19 Vaccine and all other vaccines, and as has been the case throughout the pandemic, will thoroughly evaluate new safety information."

Background

The Janssen COVID-19 Vaccine was authorized for emergency use (https://www.fda.gov/news-events/press-announcements/fda-issues-emergency-use-authorization-third-covid-19-vaccine) on Feb. 27, 2021. On April 13, 2021, the FDA and the Centers for Disease Control and Prevention (CDC), announced a recommended pause in administration (https://www.fda.gov/news-events/press-announcements/joint-cdc-and-fda-statement-johnson-johnson-covid-19-vaccine) of the vaccine to investigate six reported cases of TTS, and to help ensure that health care providers were made aware of the potential for TTS and could plan for proper recognition and management due to the unique treatment required for TTS.

On April 23, 2021, following a thorough safety evaluation, including two meetings of the CDC's Advisory Committee on Immunization Practices (ACIP), the FDA and CDC lifted the recommended pause (https://www.fda.gov/news-events/press-announcements/fda-and-cdc-lift-recommended-pause-johnson-johnson-janssen-covid-19-vaccine-use-following-thorough#:~:text=Following%20a%20thorough%20safety%20review,Johnson%20(Janssen)%20COVID%2D19) regarding the use of the Janssen COVID-19 Vaccine. The agencies confirmed a total of 15 cases of TTS had been reported to the Vaccine Adverse Event Reporting System (VAERS), including the original six reported cases, out of approximately 8 million doses administered.

These data, plus the deliberations and recommendations by the ACIP, helped with FDA's assessment that the known and potential benefits of Janssen COVID-19 Vaccine outweighed its known and potential risks in individuals 18 years of age and older. The available data suggested the chance of TTS occurring was remote, but investigation into the level of potential excess risk due to vaccination and specific

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Deputy president gives update on mandatory Covid vaccines in South Africa

Staff Writer 31 March 2022

Government has no plans to introduce a mandatory Covid-19 vaccine policy in South Africa, says deputy president David Mabuza.

"One thing we are not going to do is force people to go and vaccinate," Mabuza said in response to oral questions in parliament.

"We think (that) would be crossing the 'red line'. All we can do is encourage our people to go and vaccinate."

Mabuza added that the government instead plans to 'persuade' citizens to see the benefits of taking the vaccine through various incentives, including ongoing restrictions around gatherings that limit unvaccinated people to 1,000 people

The deputy president confirmed that the government was still planning to lift its national state of disaster and most lockdown restrictions, despite the likelihood of a fifth Covid wave in the coming weeks.

He added that the fifth Covid wave is expected to be less severe than other waves, with the country expected to have a 'base' of vaccinated people which will protect it from the devastation seen in prior waves.

While no government mandate will be introduced, planned regulations will still allow private groups to introduce their own mandates.

Discovery, the owner of South Africa's largest health-insurance administrator, and other firms have already made it compulsory for their workers to be vaccinated and seen an uptake of the shots surge as a result.

Scientists advising the government have said they expect a fifth wave of infections to hit at the end of May 2022.

South Africa's official death toll from the coronavirus passed the 100,000 mark on Wednesday, a week after the country relaxed almost all restrictions in response to a decline in new infections.

An additional 44 deaths from the disease have been reported, bringing the total to 100,020, the National Institute of Communicable Diseases said in a statement.

Read: World Health Organisation gives update on what to expect from Covid-19 in 2022

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The improvements we have made in South Africa this year: Ramaphosa

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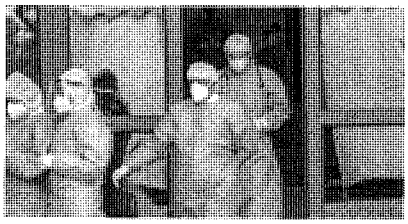

Covid deaths remain low in South Africa as positivity rate spikes

Next article

3 in-demand job skills in South Africa right now – and how much these roles pay

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26th Annual Nedlac Summit

'Recovering and Building Together'

Virtual, 07.12.2021

Key note address:

TW Nxesi MP, Minister of Employment and Labour

Protocol:

- Programme Director
- The Executive Director of Nedlac and representatives of the social partners representing Labour, Business and Communities
- Invited speakers:
    - Prof Koleka Milisana
    - Mr Valli Moosa
    - Mr Mzwanele Ntshwanti
- Members of the media
- Ladies and gentlemen

Welcome all. This has been a difficult year – indeed, almost two years since the commencement of the pandemic and the lockdowns to curb the spread of the disease, as well as the economic pain that came in their wake.

In the first year of the pandemic GDP (Gross Domestic Product) fell by over 7% and we lost well over one million jobs. And the pain continues – reflected in the most recent StatsSA unemployment figures – rising to 34.9%.

Even as we meet today, it is in the shadow of the beginnings of the Fourth Wave – with early signs that the new Omicron variant is more infectious than the Delta variant – although the indications are that symptoms are milder – with hopefully a lower rate of hospitalisations and deaths.

The pandemic placed a heavy responsibility, not only upon government, but also on the social partners and

Nedlac. I believe that in such periods of economic, social and political crisis that the need for social dialogue and strong institutions such as Nedlac becomes very apparent.

And Nedlac rose to the occasion – facilitating an all-of-society response from the social partners in a number of areas:

- Occupational health and safety regulations to safeguard the workplace from Covid-19. The evidence from the Compensation Fund is that the rate of infections in the workplace was much lower than in the community.

- More recently – the social partners have taken up the issue of workplace initiatives to vaccinate employees, whilst also taking forward the debate on mandatory vaccination. Indeed, Cabinet referred this matter to Nedlac for input from the social partners. The point must be made that the issue of health and

vaccinations goes far beyond the workplace, affecting all communities.

- Nedlac social partners also engaged around income support for laid-off workers in the form of Covid19 Ters benefits. The UIF distributed over R60 billion – supporting distressed employers and reaching millions of laid-off workers, their families, and injecting cash into local economies across the country.

- Nedlac also facilitated input from the social partners into the President's Economic Reconstruction and Recovery Plan (ERRP).

These areas remain priorities in particular:

- The finalisation of discussions around mandatory vaccination. I believe that Nedlac has provided clear advice in this regard. I quote: "*The Nedlac social partners represented in the Nedlac Rapid Response Task Team believe that the promotion of vaccines*

remains the most significant intervention to prevent further spread of Covid19 and lockdowns. To intensify the vaccination programme and in response to the President's call, they have had extensive and urgent discussion over the last week and made proposals to the government through the NatJoints that:

- *The Health and Safety Direction of the Department of Employment of Labour should be strengthened so that vaccination can become mandatory where a risk assessment at the workplace requires this.*
- *That access to certain venues, gatherings and events particularly in the hospitality sector should be restricted to vaccinated people only.*
- *Regulations on maximum capacity of gatherings/venues/events should be simplified, provision of ventilation added and enforcement strengthened so that social distancing can be adhered to.*

While, the social partners believe that vaccine mandates will pass constitutional scrutiny, they

support the work of BUSA to get a declarator from the Constitutional Court in the New Year.

They understand that their proposals will be brought to the attention of the NCCC and other relevant government structures so that decisions can be made speedily to improve the vaccination rate and mitigate the negative impact of a fourth wave." End quote.

- As the President pointed out in his Newsletter yesterday, vaccination and combating Covid is inextricably bound up with economic recovery. A further continuing priority, therefore, is the need to speed up implementation of the ERRP anchored on the following:
    - public infrastructure development;
    - Ensuring energy security;
    - Industrialization/localisation;
    - Mass Public Employment programmes;
    - Macro-economic interventions and enablers of growth;
    - Green economy interventions; Agriculture and food security; and

- Reviving the tourism sector – recognising the huge set-back as a result of what has been called the 'apartheid travel bans'.

The social partners in NEDLAC also agreed a Social Pact to drive a localisation plan of R200 billion over five years. This also led to the identification of 42 products areas across: agro-processing; health-care; basic consumer goods; capital goods; construction-driven value-chains; and transport rolling stock as focus points for SA's localization efforts. CEO champions (Chief Executive Officers) from the private sector will drive implementation of the plan – supported by government-led industry master plans across key sectors.

Cooperation between private and public sector is important to achieve these goals, whilst Government continues to work hard in developing industrial financing and incentives, and supportive regulatory systems informed by inputs from social partners.

For a maximum impact, there is a need for social partners to promote local procurement of SA manufactured goods.

The Recovery Plan also focuses on the following:

- Support to Small and Medium Enterprises (SMEs) fully aware that by 2030 no less than 90% of new jobs will be created in SMEs.
- Demand-led skills development, responding to the needs of the labour market, and
- Implementation of B-BBEE (Broad-Based Black Economic Empowerment) which provides opportunities for local entrepreneurs – previously excluded - to build capacity and compete in a globalised economic environment.

Looking ahead to 2022, as Nedlac, we are also called upon to tackle additional priorities:

- Plugging the holes in the social protection safety net – so clearly exposed during the pandemic lockdowns – for the informal sector, gig workers and the vulnerable workers in general. This will require that we take an in depth look at present provision, and would include a discussion about the very definition of what constitutes a 'worker' and an 'employee'.

- This also calls for a conversation and analysis of the impact of technological change and the Fourth Industrial Revolution on the world of work and on society in general. We know that 4IR comes with huge opportunities – and we must ensure that our people are trained and re-skilled – in a demand-led training process - to take advantage of these opportunities. Equally, we know, 4IR is going to be hugely disruptive of existing labour processes and employment patterns. Hence the need for Nedlac to take this up and chart the way forward in the interests of the many, not just the few.

- Nedlac is also called upon to address issues of energy and sustainability. The country needs a plan for coal – and to negotiate a 'just transition'. By the way, it is one year since the signing of the Eskom Social Compact – we need to show progress in this respect.

- Also, in addressing the barriers to easing the costs of doing business in South Africa, Nedlac will need to lead a review of current labour laws, regulations and processes – in order to cut red tape and administrative cost, especially for SMMEs. By the way, a general review is probably due. The present labour laws and industrial relations system were drafted and put in place over 20 years ago. There are signs that the present collective bargaining system is taking strain – and needs to be strengthened.

In concluding, the lesson of the last two years – the united rapid response to the pandemic – is that social dialogue is vital not only in the good times, but especially during a period of national disaster – in terms

of the health crisis, as well as socio-economic difficulties. We see where other societies have been torn apart by the impact of the pandemic. We must never underestimate the value of having strong institutions such as Nedlac to provide a venue and conduit for social dialogue.

In 2022, as we continue to combat Covid-19 – in its different variants – and embark upon the road of reconstruction and recovery, Nedlac will remain critical to successfully achieving our goals.

I wish you well in your deliberations – and that we live up to the theme of this Summit: 'Recovering and Building Together'.

Thank you.

risk factors continued. At that time the Fact Sheet for Healthcare Providers Administering Vaccine was revised to include a warning pertaining to the risk of TTS and the Fact Sheet for Recipients and Caregivers was also revised to include information about blood clots in combination with low blood platelets after receiving the Janssen COVID-19 Vaccine.

In December 2021, after reviewing updated vaccine effectiveness and safety data, the ACIP made a preferential recommendation for the use of mRNA COVID-19 vaccines over the Janssen COVID-19 Vaccine in all persons 18 years of age and older in the United States. The ACIP recommended and CDC endorsed that the Janssen COVID-19 Vaccine may be considered in some situations: when a person has a contraindication to receipt of mRNA COVID-19 vaccines, when a person would otherwise remain unvaccinated for COVID-19 due to limited access to mRNA COVID-19 vaccines, and when a person wants to receive the Janssen COVID-19 Vaccine despite the safety concerns identified.

Current Status

The FDA and CDC have continuously monitored for and investigated all suspected cases of TTS reported to VAERS. In an updated analysis of TTS cases following administration of the Janssen COVID-19 Vaccine that were reported to VAERS through March 18, 2022, the FDA and CDC have identified 60 confirmed cases, including nine fatal cases. The FDA has determined that the reporting rate of TTS is 3.23 per million doses of vaccine administered and the reporting rate of TTS deaths is 0.48 per million doses of vaccine administered.

In making the determination to limit the authorized use of the Janssen COVID-19 Vaccine, the agency considered that reporting rates of TTS and TTS deaths following administration of the Janssen COVID-19 Vaccine are not appreciably lower than previously reported. Furthermore, the factors that put an individual at risk for TTS following administration of Janssen COVID-19 Vaccine remain unknown. The FDA also considered that individuals with TTS may rapidly deteriorate, despite prompt diagnosis and treatment, that TTS can lead to long-term and debilitating health consequences and that TTS has a high death rate. The agency also considered the availability of alternative authorized and approved COVID-19 vaccines which provide protection from COVID-19 and have not been shown to present a risk for TTS.

Examples of individuals who may still receive the Janssen COVID-19 Vaccine include: individuals who experienced an anaphylactic reaction after receipt of an mRNA COVID-19 vaccine, individuals who have personal concerns with receiving mRNA vaccines and would otherwise not receive a COVID-19 vaccine and individuals who would remain unvaccinated for COVID-19 due to limited access to mRNA COVID-19 vaccines.

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NATIONAL ECONOMIC DEVELOPMENT AND LABOUR COUNCIL

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Attention News Editors/Business and Labour reporters

Date: December 8, 2021

Nedlac's social partners contribution to fight the Covid19 pandemic recognised

Johannesburg, South Africa: At Nedlac's 26th Annual National Summit in Johannesburg held yesterday, Minister of Employment and Labour, Thembelani Thulas Nxesi congratulated the social partners for their collective effort to fight the Covid19 pandemic.

Ms. Boitumelo Moloi, the Deputy Minister in the Department of Employment and Labour, was present at the summit. Speakers included Nedlac Executive Director Lisa Seftel, Valli Moosa, deputy chair of the Presidential Climate Change Coordinating Commission, economist Mzwanele Ntshwanti, economist, and Professor Koleka Mlisana, Chairperson of the Ministerial Advisory Committee (MAC) of Covid-19, and Executive Manager Research and Quality Assurance at the National Health Laboratory Service.

Overall community convenor Thulani Tshefuta, and labour convenor Bheki Ntshalintshali, and CEO for Business Unity South Africa Cas Coovadia also provided their reflections on behalf of their constituencies.

The summit is held annually to inform the public of achievements, reflect on the past year and identify issues for the year ahead. This year it was held online with a focus on the key issues facing South Africa including the economic crisis, high levels of unemployment, the imperative to address climate change and the impact of the Covid19 pandemic.

Minister Nxesi said that in such periods of economic social and political crisis "the need for social dialogue and strong institutions such as Nedlac become very apparent".

He said Nedlac facilitated an all-of-society response from the social partners in a number of areas including enhancing occupations health and safety to safeguard the workplace from Covid-19.

There is a consensus on the need to promote vaccinations to prevent further lockdown, loss of lives and livelihoods. There is further consensus

that vaccinations is an effective way to do this and in the face of Omicron variant, social partners have put proposals to government on mandatory vaccination in workplace and only vaccinated allowed entry.

The Minister quoted the position of the Nedlac Rapid Response Task which states that health and safety direction of his department should be strengthened so that vaccination can become mandatory where a risk assessment at the workplace requires this.

While, the social partners believed that vaccine mandates will pass constitutional scrutiny, they supported the work of Business Unity South Africa (BUSA) to get a declarator from the Constitutional Court to seek an order for compulsory Covid-19 vaccination in the workplace, the minister said.

Seftel in her presentation on Nedlac's performance said: "The devastation of the Covid-19 pandemic would have been even more severe if it had not been for the collective efforts of the social partners on issues of relief, vaccinations and collaborating on regulations to safely open up the economy.

"The most important measures that all social partners agree on is that ramping up vaccinations, including through positive and negative incentives, is critical, as well as the ongoing promotions of pharmaceutical interventions," said Seftel.

The Unemployment Fund distributed over R63 billion in terms of the Covid-19 Ters benefits – supporting distressed employers and reaching millions of laid-off workers, their families, and injecting cash into local economies across the country.

Seftel said the social partners had responded speedily to the "Eight days in July" crisis in Gauteng and KwaZulu-Natal in which various businesses were destroyed. The partners met to stabilize the country, securing essential supplies, provide relief and support the re-establishment of businesses.

After President Cyril Ramaphosa announced the Economic Reconstruction and Recovery Plan (ERRP), Nedlac set up processes to track the implementation of commitments and collaborate in identified areas.

Various structures were set up and areas of focus were identified, including the unlocking of blockages in freight and improving public transport.

Minister Nxesi told the summit how Nedlac should look ahead tackling various priorities including plugging the holes in the social protection safety net for the informal sector, gig workers and the vulnerable workers in general. He said people should be trained for technological change and the Fourth Industrial Revolution which was hugely disruptive of existing labour processes and employment patterns.

Minister Nxesi said Nedlac will be called upon to address issues of energy and sustainability. The country needed a plan for coal – and to negotiate a "just transition". Valli Moosa, deputy chairperson of the Presidential Climate Commission invited to share his reflections on the impact of climate change, said that South Africa had significant opportunities in the climate transition as it had some of the best renewable energy resources in the world.

"The good news is that a future green economy will create more jobs in new low-carbon sectors than are lost in declining fossil fuel sectors," he said.

Also presenting at the summit, Professor Koleka Mlisana, Executive Manager of the National Health Laboratory Services and Chairperson of the Ministerial Advisory Committee, said that there were several lessons that had been learned from Covid-19 and previous pandemics.

She said the pandemic had biological and social drivers. While science was addressing the biological, behavioural modification is key for the social drivers. She added the antisocial drivers included the impact of alcohol on health systems and family structure; corruption and accountability related to COVID-19 resources.

There should be an "urgent plan to translate from containment to mitigation - learning to live with SARS-CoV-2", she said.

In the responses of the social partners, Cas Coovadia, speaking for organised business said that while 2020-2021 was a challenging year due to Covid, the July unrest, the dwindling economy and the political climate, Nedlac had done well and should draw lessons from its interventions.

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Thulani Tshefuta, overall community convener, following the summit, said: "We must follow the economic patterns that inform the changing nature of work and adapt accordingly. We are also keen to see improved collective implementation of the commitments of ERRP by social partners."

Labour convenor Bheki Ntshalintshali said it was important for the public to reflect on Nedlac's performance report and give their feedback. He added it was a lost opportunity that government did not report on the performance or lack of progress of the ERRP (aimed at stimulating equitable and inclusive growth) which was implemented one year old.

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Issued by FBI Communications on behalf of Nedlac

[ENDS]

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"Nedlac social partners have discussed and agreed on a Code of Good Practice under the Labour Relations Act which sets out what workplaces should do to manage Covid-19, " said Executive Director of Nedlac Lisa Seftel on Newzroom Afrika tonight. #COVID19

10:16 PM · Mar 30, 2020 · Twitter for Phone

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Lisa Seftel added that measures were recommended to curb any unfair dismissal that could ensue in the workplace in an effort to...
#COVID19

XII

KRIEK WASSENAAR & VENTER ING
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13 April 2022

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PRETORIA

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Minister/Sir/Madam

NATIONAL EMPLOYERS' ASSOCIATION OF SOUTH AFRICA (NEASA) / THE MINISTER OF EMPLOYMENT AND LABOUR / IN RE: CODE OF PRACTICE: MANAGING EXPOSURE TO SARS-COV-2 IN THE WORKPLACE, 2022 (15 FEBRUARY 2022) / HAZARDOUS BIOLOGICAL AGENTS REGULATIONS, 2022 (16 MARCH 2022)

1. We act on the instructions of the National Employers' Association of South Africa ("NEASA") ("our client").

2. Our client has noted the recent publication of the following regulations in the Government Gazette:

   2.1 the Code of Practice: Managing exposure to SARS-CoV-2 in the workplace, 2022 (GG 46043) of 15 February 2022 (hereinafter referred to as "the Code");

   2.2 the Hazardous Biological Agents Regulations, 2022 (GG 46051) of 16 March 2022 (hereinafter referred to as "the HBA").

3. It is our client's position that the regulations above should be withdrawn. Our client believes that the HBA and the Code improperly infringe upon the workplace rights of both employees and employers.

THE CODE

4. The Minister has published the Code in terms of section 203 (2A) of the Labour Relations Act, 66 of 1995 (the "LRA"), ostensibly in order to manage *exposure to SARS-CoV-2 and the workplace.*

5. The Code includes various salient features that directly and indirectly seek to create a system of mandatory vaccinations in the workplace and legitimise the limitation of the Constitutional rights of persons who choose not to get vaccinated.

6. Our client believes that the Code has been framed more in line with regulations than a code of good practice, which it presents itself to be. On gleaning the document, it is clear that the Code provides more than a mere guideline for employers to follow regarding the management of SARS-CoV-2 in the workplace. The Code is in many respects prescriptive to such an extent that it creates a new corpus of labour law. Consider *inter alia,* the following departures from the current body of law:

   6.1 Sections 5 and 14 - make it obligatory for employers to undertake risk assessments in terms of the Occupational Health and Safety Act, 85 of 1993 ("OSHA") and the HBA regulations, despite the limited application of OSHA and the HBA to certain classes of business.

   6.2 Section 12(1) (a) - the Code authorises the creation of mandatory vaccination schemes drafted by an employer in the workplace. However, if consideration is given to section 13 of the Code, it seems as if the Minister holds a different position regarding vaccination as a workplace safety issue in smaller companies.

   6.3 Section 12 (2) - the Code gives employers the right to demand the disclosure of an employee's medical and medical treatment status;

   6.4 Sections 12 (5) and (6) – exclude Constitutional defences against vaccination;

   6.5 Section 15 – creates a new personal right to strike or refuse work, which an employee may rely on (ostensibly based on new SARS-CoV-2 health and safety norms).

   6.6 Section 17 – fashions hodgepodge empowering legislation under both the LRA and the OSHA to create a new form of compliance and enforcement officers under the Code.

7. Our client's position is that the Minister has acted *ultra vires* the powers granted to the Minister under section 203(2A) of the LRA. The Code is not a code of good practice in the manner intended by the enabling provisions of section 203 and the LRA. Section 203 does not empower the Minister to limit or encroach upon any Constitutional rights (we can refer to sections 1(a), 1(c), 2, 7, 9, 10, 12, 14, 15, 23(1), and 36 of the Constitution). The section also does not afford the Minister the legal authority to amend or interfere with statutory and common law rights, as there is no clear indication that the legislature could have anticipated or considered the current scope of regulations contained in the Code.

8. Our client has noted various press releases issued by the Minister's department as well as the National Economic Development and Labour Council (NEDLAC), indicating that the Code was not only the result of consultation and agreement between the Minister and NEDLAC but also specifically as a result of consensus amongst NEDLAC partners. If this is true, the Minister's Code has been created in contravention of section 203(2A), which limits the powers of the Minister regarding the creation of so-called codes of good practice.

THE HBA

9. The Minister on 16 March 2022 classified SARS-CoV-2 as a risks group 3 hazardous biological agent under the HBA regulations to the OHSA.

10. It is our client's position that the HBA has misaligned itself with the scope and purpose of the OHSA in so far as it now includes SARS-CoV-2. Our client believes that it is inappropriate and administratively irregular to classify SARS-COV-2 as a hazardous biological agent. SARS-CoV-2 is not a pathogen arising out of or in relation to the workplace and cannot be classified as an occupational health and safety issue.

11. Therefore, the inclusion of SARS-CoV-2 in the HBA is irrational, unreasonable and ultra vires the empowering legislation.

12. Even if it is found that the inclusion of SARS-CoV-2 in the HBA is not administratively improper, the application of the HBA in the Code is. The HBA regulations are clearly aimed at managing hazardous biological agents under an employer's control. To apply the HBA to all employers, as the Code attempts to do, is irrational and unreasonable.

UNCONSTITUTIONAL APPROACH

13. Our client's most significant concern lies with the Minister's approach to regulating SARS-CoV-2 in the workplace. The Minister is prejudiced toward managing the spread of the virus via the mandatory vaccination of the public.

14. Our client implores the Minister to abandon this ill-conceived approach.

15. None of the features of the currently available vaccines supports the argument that mandatory vaccination policies are reasonable or necessary. Our client's understanding of the science relating to the currently available vaccines is that the vaccines 1) do not prevent infection, 2) do not prevent the spread of the virus and 3) do not prevent variants and/or mutations. Accordingly, vaccination as a means to manage workplace health and safety is irrational and unreasonable.

16. Mandatory vaccination policies severely infringe upon the bodily integrity and human dignity of persons who are required to undergo such compulsory medical treatment. These victims are either stripped of their right to make informed medical choices or relegated to a class of second-hand citizens who cannot participate in the ordinary workforce if they choose to rely on their Constitutional rights.

17. Our client does not share government's position that vaccines are entirely safe. For instance, the Pfizer Comirnaty vaccine has almost 1300 recorded possible side effects, many of which can severely injure a person (or even result in their death). If we consider the severe personal price that a person might have to pay as a result of vaccination, nothing less than complete voluntary vaccination can stand up to Constitutional muster.

18. We have been requested to demand that the Minster:

    18.1 withdraw the Code in toto; and

    18.2 withdraw the classification of SARS-CoV-2 as a risk Group 3 hazardous biological agent under the HBA;

    18.3 provide a firm undertaking that the Minster will not publish further regulations which seeks:

        18.3.1 to discriminate against people based on their vaccination status;

18.3.2 authorises the creation of mandatory vaccination schemes or programmes which compel employers and/or employees to consider mandatory vaccination as part of any workplace policy;

18.3.3 compel a person to disclose his/her vaccination status;

18.3.4 creates rules which will support or otherwise allow for the dismissal of any person as a result of their medical choices;

18.3.5 penalise or prosecute any person who refuses to apply or otherwise comply with a vaccination policy;

18.3.6 encroaches on or limits a person's right to bodily integrity and ability to make voluntary informed medical decisions.

19. We require a response to this letter by no later than 20 April 2022; failing thereto, our client has instructed us to proceed with an application in the High Court. Our instructions are to seek various orders for the review and setting aside of the Code and the aggrieving provisions of the HBA. We also hold instructions to seek general Constitutional relief.

Yours faithfully,

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Date: 25 April 2022

Attention: P J Wassenaar

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Direkteur / Director

By email: peter@kriekprok.co.za

RE: YOUR LETTER OF 13 APRIL 2022

Dear Sir,

I trust that this letter finds you well.

The Department has taken note of your views in relation to the Code of Practice: Managing exposure to SARS-CoV-2 in the workplace ("The Code") as published on the15th of March 2022 and responds as follows:

1. The Minister wishes to indicate that the purpose on the published code is just as it states in clause 2 thereof. This code serves to provide guidance to employers and employees in managing exposure to SARS-CoV-2 within the workplace.

2. When one reads clause 2, it is clear that the Minister deemed it necessary for the employers to engage in a risk assessment plan that would determine their response to mitigating the exposure to the SARS-CoV-2 virus within the workplace.

3. In clause 7(2) (c) of the code it is evident that the Minister takes note of the risks associated with the vaccines.

   The Minister's views on risks of the vaccine can be noted in clause 7 (2) (c) of the Code which contemplates as follows:

   " the employer must provide workers with information that raises awareness in any form or manner, including, where reasonably practicable, leaflets and notices placed in conspicuous places in the workplace informing workers of-

   (c) the nature of vaccines used in the country, the benefits associated with these COVID-19 vaccines, the contra-indications for vaccination and the nature and risk of any serious side effects".

4. The Minister denies that the code in question imposes compulsory or mandatory vaccinations within the workplace. The Code however, guides employers that wish to resort to mandatory vaccinations in their risk assessment plan as a response to the exposure to the SARS –CoV-2 virus in their workplaces. Further, as can be noted in clause 12(4) of the Code as quoted below, it expressly indicates that the employer must take reasonable steps to accommodate employees who refuse to be vaccinated.

   Clause 12(4) contemplates as follows:

   "If an employee refuses to be vaccinated, the employer **must**-

   (a) counsel the employee and, if requested, allow the employee to seek guidance from a health and safety representative, worker representative or trade union official;

   (b) take steps to reasonably accommodate the employee in a position that does not require the employee to be vaccinated.

   It is thus clear that the code is not prescriptive of mandatory vaccinations.

5. In so far as the classification of SARS-CoV-2 as a hazardous biological agent is concerned the Minister responds as follows:

5.1 The SARS-Cov-2 is part of the family of Coronavirinae which was included in the list of "Categorization of Biological Agents according to Hazard and Categories of Containment" indicated as Annexure B in the previous Hazardous Biological Agent Regulations (The HBA regulations"). As a result, SARS-CoV-2 virus was classified as a hazardous biological agent as defined in the regulations in question. Another important consideration that the Minister took into account is the fact that similar to the Mycobacterium tuberculosis, the SARS-Cov-2 can be contracted both from the workplace and outside of the workplace.

5.2 Prior to the publishing the Regulations for HBA regulations Agents the Minister engaged in a widely consultative process that included its publishing for public comment. Further, the Department of Employment and Labour ("the Department") held webinars with stakeholders in order to engage them on the draft HBA regulations.

The Minister thus differs from your view that the inclusion of SARS-CoV-2 is in these regulations is improper, irrational and ultra vires.

6. After careful considerations of the content of your letter, the Minister has decided not to withdraw the classification SARS-CoV-2 as category risk 3 hazardous biological agent of HBA regulations nor the Code of Practice: Managing exposure to SARS-CoV-2 of 2022.

7. The Minister denies that the Code specifically aims to discriminate against certain groups of people in the workplace based on their constitutional rights and beliefs.

Yours faithfully,

PP: For the Director – General: Employment& Labour

OVERVIEW BY THE CHIEF ELECTORAL OFFICER

The Electoral Commission is honoured to present the 2021 Municipal Elections Report, which covers elections that were challenging, exciting and historic.

This report is presented in pursuance of Section 14(3) of the Electoral Commission Act (Act No 51 of 1996) and sets out the activities undertaken during the total electoral cycle for the 2021 Municipal Elections held on 1 November 2021.

These elections were historic in that they were held under conditions imposed by COVID-19. This public health crisis posed many unprecedented challenges in the preparation for and holding of elections. Faced with these challenges, our duty was to preserve the integrity of the Commission, the electoral process, and election outcomes as required in terms of the Constitution of the Republic of South Africa. We were able to do so with pleasing efficiency, because our focus was on delivering the best elections possible, despite the challenges.

The decision that the Commission took to create a transparent process – chaired by retired Deputy Chief Justice Dikgang Moseneke – on whether free and fair elections were possible within the COVID-19 context, was a necessity.

We are proud to report that, throughout the disruptions brought about by COVID-19, the Commission continued to function in compliance with prescripts. Therefore, once the legal challenges were dispensed with, it was possible to deliver elections in 42 days – the shortest period in the history of our electoral democracy.

With so many challenges, we experienced inexcusable ills, but they are part of the elections environment. However, delivering, as we did, a registration weekend in 14 days was a major achievement. Equally, delivering an election in 42 days was the second major positive landmark.

For the staff at the Commission, delivering these elections was a big call and it is one that they answered with aplomb. For that, the Commission remains eternally grateful to each one of them.

Electoral Commission Chief Electoral Officer, Simon Mamabolo

In keeping with our constitutional commitment of being inclusive, our electoral engagement had a social consciousness and was thus alive to the fact that we have, among us, those who are infirm or with impaired mobility. Hence, South Africans in special circumstances were offered an opportunity to cast special votes on 30 and 31 October 2021.

Special votes served a twin purpose: on the one hand, they enfranchised people in special circumstances and assisted with the depopulation of voting stations on Elections Day in line with COVID-19 protocols. They also offered the Commission an opportunity to sharpen the proficiency of its operations ahead of Voting Day.

Without a doubt, the 2021 Municipal Elections will go down in history as the most innovative. The use of voter management devices (VMDs) catapulted electoral management in our country to new heights, setting a foundation for future innovations. Yes, operational challenges were encountered, but despite that, the VMDs were a success we can all be proud of.

The Commission deployed 30 387 VMDs, which were centrally connected through an Access Point Network.

This digital connection enabled the strengthening of controls in the voting process. Once ballots had been issued to a voter, voters could not present themselves at another voting station without detection. In use at the voting stations was a live, centrally connected voters' roll. This capability will decisively lay to rest allegations of double voting.

With the VMD, possibilities abound. The prospect of building additional engines and reports will enable the real-time monitoring of the quantities of ballot papers issued and on hand at each voting station. This will remedy the reports of voting stations running out of ballot papers.

Therefore, the introduction of VMDs can only serve to fortify controls in the voting process and enhance the capability to manage the voting process efficiently. The challenges of the moment, as we experienced, should not cloud our desire to exploit digital innovations to improve our electoral programmes. We dare not retard the progress we have made.

Our electoral enterprise is about people and their well-being. So, the views expressed by voters through a survey conveyed by the Human Sciences Research Council (HSRC) are important.

The HSRC interviewed 12 189 randomly sampled voters in 300 voting stations across the country during different time segments throughout Voting Day. By acceptable standards, this is a representative sample that enables us to make generalisations of the whole voter population.

Some 97% of the sampled voters found the voting procedures inside our voting stations easy to understand, while 94% was satisfied with the ballot papers used in the elections. In other words, the identifiers used in the ballot design were clear and not confusing to voters.

This survey further indicated that 96% was satisfied with the secrecy of the ballot, while 93% was satisfied with the safety and security at voting stations. Some 84% expressed confidence in the accuracy of the counting and tallying processes. Most importantly, 95% experienced the elections as being free and fair.

We are also glad that this survey reflects that 93% of the voters commended the Commission's efforts to mitigate the risk of COVID-19 at the voting stations.

Overall, voters said their lived electoral reality was positive and consistent with their expectations of integrity standards in the voting process.

The people have indeed spoken.

This is a solid foundation on which we will build future electoral operations. The Commission will continue to work with all its stakeholders to improve the voter experience.

I echo the gratitude expressed by the Vice-Chairperson to all stakeholders and our staff for the role they played in delivering good-quality, free and fair municipal elections in South Africa.

Simon Mamabolo
Chief Electoral Officer
Electoral Commission of South Africa

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Community transmission and viral load kinetics of the SARS-CoV-2 delta (B.1.617.2) variant in vaccinated and unvaccinated individuals in the UK: a prospective, longitudinal, cohort study

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Summary

Background The SARS-CoV-2 delta (B.1.617.2) variant is highly transmissible and spreading globally, including in populations with high vaccination rates. We aimed to investigate transmission and viral load kinetics in vaccinated and unvaccinated individuals with mild delta variant infection in the community.

Methods Between Sept 13, 2020, and Sept 15, 2021, 602 community contacts (identified via the UK contract-tracing system) of 471 UK COVID-19 index cases were recruited to the Assessment of Transmission and Contagiousness of COVID-19 in Contacts cohort study and contributed 8145 upper respiratory tract samples from daily sampling for up to 20 days. Household and non-household exposed contacts aged 5 years or older were eligible for recruitment if they could provide informed consent and agree to self-swabbing of the upper respiratory tract. We analysed transmission risk by vaccination status for 231 contacts exposed to 162 epidemiologically linked delta variant-infected index cases. We compared viral load trajectories from fully vaccinated individuals with delta infection (n=29) with unvaccinated individuals with delta (n=16), alpha (B.1.1.7; n=39), and pre-alpha (n=49) infections. Primary outcomes for the epidemiological analysis were to assess the secondary attack rate (SAR) in household contacts stratified by contact vaccination status and the index cases' vaccination status. Primary outcomes for the viral load kinetics analysis were to detect differences in the peak viral load, viral growth rate, and viral decline rate between participants according to SARS-CoV-2 variant and vaccination status.

Findings The SAR in household contacts exposed to the delta variant was 25% (95% CI 18–33) for fully vaccinated individuals compared with 38% (24–53) in unvaccinated individuals. The median time between second vaccine dose and study recruitment in fully vaccinated contacts was longer for infected individuals (median 101 days [IQR 74–120]) than for uninfected individuals (64 days [32–97], p=0·001). SAR among household contacts exposed to fully vaccinated index cases was similar to household contacts exposed to unvaccinated index cases (25% [95% CI 15–35] for vaccinated *vs* 23% [15–31] for unvaccinated). 12 (39%) of 31 infections in fully vaccinated household contacts arose from fully vaccinated epidemiologically linked index cases, further confirmed by genomic and virological analysis in three index case–contact pairs. Although peak viral load did not differ by vaccination status or variant type, it increased modestly with age (difference of 0·39 [95% credible interval −0·03 to 0·79] in peak $\log_{10}$ viral load per mL between those aged 10 years and 50 years). Fully vaccinated individuals with delta variant infection had a faster (posterior probability >0·84) mean rate of viral load decline (0·95 $\log_{10}$ copies per mL per day) than did unvaccinated individuals with pre-alpha (0·69), alpha (0·82), or delta (0·79) variant infections. Within individuals, faster viral load growth was correlated with higher peak viral load (correlation 0·42 [95% credible interval 0·13 to 0·65]) and slower decline (−0·44 [−0·67 to −0·18]).

Interpretation Vaccination reduces the risk of delta variant infection and accelerates viral clearance. Nonetheless, fully vaccinated individuals with breakthrough infections have peak viral load similar to unvaccinated cases and can efficiently transmit infection in household settings, including to fully vaccinated contacts. Host–virus interactions early in infection may shape the entire viral trajectory.

Funding National Institute for Health Research.

Introduction

While the primary aim of vaccination is to protect individuals against severe COVID-19 disease and its consequences, the extent to which vaccines reduce onward transmission of SARS-CoV-2 is key to containing the pandemic. This outcome depends on the ability of

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See Comment page 152

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Research in context

Evidence before this study

The SARS-CoV-2 delta variant is spreading globally, including in populations with high vaccination coverage. While vaccination remains highly effective at attenuating disease severity and preventing death, vaccine effectiveness against infection is reduced for delta. Determining the extent of transmission from vaccinated delta-infected individuals to their vaccinated contacts is a public health priority. Comparing the upper respiratory tract (URT) viral load kinetics of delta infections with those of other variants gives insight into potential mechanisms for its increased transmissibility. We searched PubMed and *medRxiv* for articles published between database inception and Sept 20, 2021, using search terms describing "SARS-CoV-2, delta variant, viral load, and transmission". Two studies longitudinally sampled the URT in vaccinated and unvaccinated delta variant-infected individuals to compare viral load kinetics. In a retrospective study of a cohort of hospitalised patients in Singapore, more rapid viral load decline was found in vaccinated individuals than unvaccinated cases. However, the unvaccinated cases in this study had moderate-to-severe infection, which is known to be associated with prolonged shedding. The second study longitudinally sampled professional USA sports players. Again, clearance of delta viral RNA in vaccinated cases was faster than in unvaccinated cases, but only 8% of unvaccinated cases had delta variant infection, complicating interpretation. Lastly, a report of a single-source nosocomial outbreak of a distinct delta sub-lineage in Vietnamese health-care workers plotted viral load kinetics (without comparison with unvaccinated delta infections) and demonstrated transmission between fully vaccinated health-care workers in the nosocomial setting. The findings might therefore not be generalisable beyond the particular setting and distinct viral sub-lineage investigated.

Added value of this study

The majority of SARS-CoV-2 transmission occurs in households, but transmission between fully vaccinated individuals in this setting has not been shown to date. To ascertain secondary transmission with high sensitivity, we longitudinally followed index cases and their contacts (regardless of symptoms) in the community early after exposure to the delta variant of SARS-CoV-2, performing daily quantitative RT-PCR on URT samples for 14–20 days. We found that the secondary attack rate in fully vaccinated household contacts was high at 25%, but this value was lower than that of unvaccinated contacts (38%). Risk of infection increased with time in the 2–3 months since the second dose of vaccine. The proportion of infected contacts was similar regardless of the index cases' vaccination status. We observed transmission of the delta variant between fully vaccinated index cases and their fully vaccinated contacts in several households, confirmed by whole-genome sequencing. Peak viral load did not differ by vaccination status or variant type but did increase modestly with age. Vaccinated delta cases experienced faster viral load decline than did unvaccinated alpha or delta cases. Across study participants, faster viral load growth was correlated with higher peak viral load and slower decline, suggesting that host–virus interactions early in infection shape the entire viral trajectory. Since our findings are derived from community household contacts in a real-life setting, they are probably generalisable to the general population.

Implications of all the available evidence

Although vaccines remain highly effective at preventing severe disease and deaths from COVID-19, our findings suggest that vaccination is not sufficient to prevent transmission of the delta variant in household settings with prolonged exposures. Our findings highlight the importance of community studies to characterise the epidemiological phenotype of new SARS-CoV-2 variants in increasingly highly vaccinated populations. Continued public health and social measures to curb transmission of the delta variant remain important, even in vaccinated individuals.

vaccines to protect against infection and the extent to which vaccination reduces the infectiousness of breakthrough infections.

Vaccination was found to be effective in reducing household transmission of the alpha variant (B.1.1.7) by 40–50%,[1] and infected, vaccinated individuals had lower viral load in the upper respiratory tract (URT) than infections in unvaccinated individuals,[2] which is indicative of reduced infectiousness.[3,4] However, the delta variant (B.1.617.2), which is more transmissible than the alpha variant,[5,6] is now the dominant strain worldwide. After a large outbreak in India, the UK was one of the first countries to report a sharp rise in delta variant infection. Current vaccines remain highly effective at preventing admission to hospital and death from delta infection.[7] However, vaccine effectiveness against infection is reduced for delta, compared with alpha,[8,9] and the delta variant continues to cause a high burden of cases even in countries with high vaccination coverage. Data are scarce on the risk of community transmission of delta from vaccinated individuals with mild infections.

Here, we report data from a UK community-based study, the Assessment of Transmission and Contagiousness of COVID-19 in Contacts (ATACCC) study, in which ambulatory close contacts of confirmed COVID-19 cases underwent daily, longitudinal URT sampling, with collection of associated clinical and epidemiological data. We aimed to quantify household transmission of the delta variant and assess the effect of vaccination status on contacts' risk of infection and index cases' infectiousness, including (1) households with unvaccinated contacts and index cases and (2) households with fully vaccinated contacts and fully vaccinated index cases. We also compared sequentially sampled

URT viral RNA trajectories from individuals with non-severe delta, alpha, and pre-alpha SARS-CoV-2 infections to infer the effects of SARS-CoV-2 variant status—and, for delta infections, vaccination status—on transmission potential.

Methods

Study design and participants

ATACCC is an observational longitudinal cohort study of community contacts of SARS-CoV-2 cases. Contacts of symptomatic PCR-confirmed index cases notified to the UK contact-tracing system (National Health Service Test and Trace) were asked if they would be willing to be contacted by Public Health England to discuss participation in the study. All contacts notified within 5 days of index case symptom onset were selected to be contacted within our recruitment capacity. Household and non-household contacts aged 5 years or older were eligible for recruitment if they could provide written informed consent and agree to self-swabbing of the URT. Further details on URT sampling are given in the appendix (p 13).

The ATACCC study is separated into two study arms, ATACCC1 and ATACCC2, which were designed to capture different waves of the SARS-CoV-2 pandemic. In ATACCC1, which investigated alpha variant and pre-alpha cases in Greater London, only contacts were recruited between Sept 13, 2020, and March 13, 2021. ATACCC1 included a pre-alpha wave (September to November, 2020) and an alpha wave (December, 2020, to March, 2021). In ATACCC2, the study was relaunched specifically to investigate delta variant cases in Greater London and Bolton, and both index cases and contacts were recruited between May 25, and Sept 15, 2021. Early recruitment was focused in West London and Bolton because UK incidence of the delta variant was highest in these areas.[10] Based on national and regional surveillance data, community transmission was moderate-to-high throughout most of our recruitment period.

This study was approved by the Health Research Authority. Written informed consent was obtained from all participants before enrolment. Parents and caregivers gave consent for children.

Data collection

Demographic information was collected by the study team on enrolment. The date of exposure for non-household contacts was obtained from Public Health England. COVID-19 vaccination history was determined from the UK National Immunisation Management System, general practitioner records, and self-reporting by study participants. We defined a participant as unvaccinated if they had not received a single dose of a COVID-19 vaccine at least 7 days before enrolment, partially vaccinated if they had received one vaccine dose at least 7 days before study enrolment, and fully vaccinated if they had received two doses of a COVID-19 vaccine at least 7 days before study enrolment. Previous literature was used to determine the 7-day threshold for defining vaccination status.[11–13] We also did sensitivity analyses using a 14-day threshold. The time interval between vaccination and study recruitment was calculated. We used WHO criteria[14] to define symptomatic status up to the day of study recruitment. Symptomatic status for incident cases—participants who were PCR-negative at enrolment and subsequently tested positive—was defined from the day of the first PCR-positive result.

Laboratory procedures

SARS-CoV-2 quantitative RT-PCR, conversion of ORF1ab and envelope (E-gene) cycle threshold values to viral genome copies, whole-genome sequencing, and lineage assignments are described in the appendix (pp 13–14).

Outcomes

Primary outcomes for the epidemiological analysis were to assess the secondary attack rate (SAR) in household contacts stratified by contact vaccination status and the index cases' vaccination status. Primary outcomes for the viral load kinetics analysis were to detect differences in the peak viral load, viral growth rate, and viral decline rate between participants infected with pre-alpha versus alpha versus delta variants and between unvaccinated delta-infected participants and vaccinated delta-infected participants.

See Online for appendix

We assessed vaccine effectiveness and susceptibility to SARS-CoV-2 infection stratified by time elapsed since receipt of second vaccination as exploratory analyses.

Statistical analysis

To model viral kinetics, we used a simple phenomenological model of viral titre[15] during disease pathogenesis. Viral kinetic parameters were estimated on a participant-specific basis using a Bayesian hierarchical model to fit this model to the entire dataset of sequential cycle threshold values measured for all participants. For the 19 participants who were non-household contacts of index cases and had a unique date of exposure, the cycle threshold data were supplemented by a pseudo-absence data point (ie, undetectable virus) on the date of exposure. Test accuracy and model misspecification were modelled with a mixture model by assuming there was a probability p of a test giving an observation drawn from a (normal) error distribution and probability $1-p$ of it being drawn from the true distribution.

The hierarchical structure was represented by grouping participants based on the infecting variant and their vaccination status. A single-group model was fitted, which implicitly assumes that viral kinetic parameters vary by individual but not by variant or vaccination status. A four-group model was also explored, where groups 1, 2, 3, and 4 represent pre-alpha, alpha, unvaccinated delta, and fully vaccinated delta, respectively. We fitted a correlation matrix between

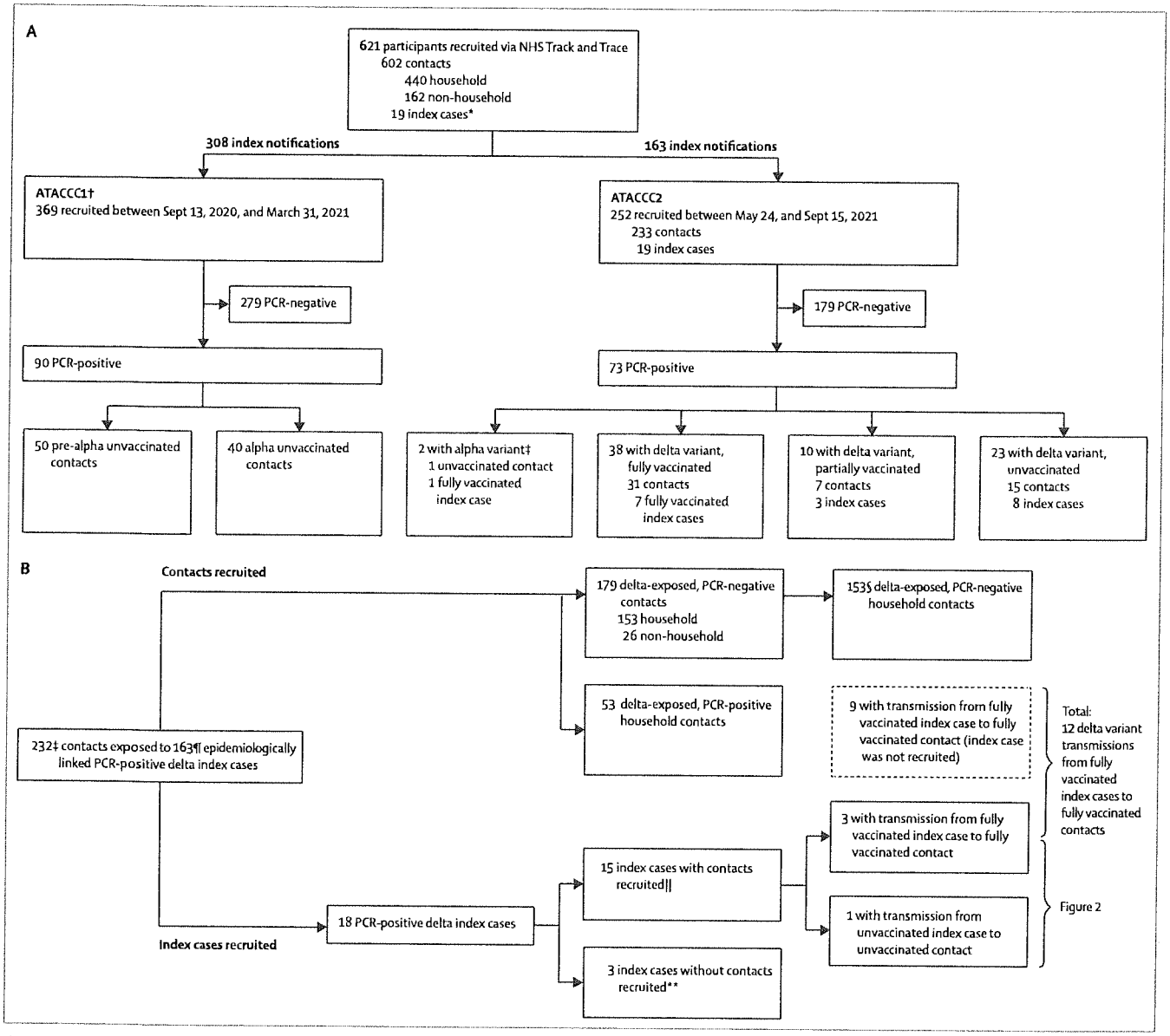


Figure 1: **Recruitment, SARS-CoV-2 infection, variant status, and vaccination history for ATACCC study participants**
(A) Study recruitment and variant status confirmed by whole-genome sequencing (ATACCC1 and ATACCC2 combined). (B) ATACCC2: delta-exposed contacts included in secondary attack rate calculation (table 1) and transmission assessment (table 2). NHS=National Health Service. *All index cases were from ATACCC2. †All contacts. ‡The two earliest PCR-positive cases from the ATACCC2 cohort (one index case and one contact) were confirmed as having the alpha variant on whole-genome sequencing (recruited on May 28, 2021). This alpha variant-exposed, PCR-positive contact is excluded from figure 1B. §One PCR-negative contact had no vaccination status data available and one PCR-negative contact's index case had no vaccination data available. ¶Vaccination data were available for 138 index cases of 163. ||The contacts of these 15 index cases are included within the 232 total contacts. **These three index cases without contacts are only included in the viral load kinetics analysis (figure 3) and are not included in tables 1 and 2.

participant-specific kinetic parameters to allow us to examine whether there is within-group correlation between peak viral titre, viral growth rate, and viral decline rate. Our initial model selection, using leave-one-out cross-validation, selected a four-group hierarchical model with fitted correlation coefficients between individual-level parameters determining peak viral load and viral load growth and decline rates (appendix p 5). However, resulting participant-specific estimates of peak viral load (but not growth and decline rates) showed a marked and significant correlation with age in the exploratory analysis, which motivated examination of models where mean peak viral load could vary with age. The most predictive model overall allowed mean viral

load growth and decline rates to vary across the four groups, with mean peak viral load common to all groups but assumed to vary linearly with the logarithm of age (appendix p 5). We present peak viral loads for the reference age of 50 years with 95% credible intervals (95% CrIs). 50 years was chosen as the reference age as it is typical of the ages of the cases in the whole dataset and the choice of reference age made no difference in the model fits or judgment of differences between the groups.

We computed group-level population means and within-sample group means of log peak viral titre, viral growth rate, and viral decline rate. Since posterior estimates of each of these variables are correlated across groups, overlap in the credible intervals of an estimate for one group with that for another group does not necessarily indicate no significant difference between those groups. We, therefore, computed posterior probabilities, *pp*, that these variables were larger for one group than another. For our model, Bayes factors can be computed as $pp/(1-pp)$. We only report population (group-level) posterior probabilities greater than 0·75 (corresponding to Bayes factors >3) as indicating at least moderate evidence of a difference.

For vaccine effectiveness, we defined the estimated effectiveness at preventing infection, regardless of symptoms, with delta in the household setting as 1 – SAR (fully vaccinated) / SAR (unvaccinated).

Role of the funding source

The funder of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report.

Results

Between Sept 13, 2020, and Sept 15, 2021, 621 community-based participants (602 contacts and 19 index cases) from 471 index notifications were prospectively enrolled in the ATACCC1 and ATACCC2 studies, and contributed 8145 URT samples. Of these, ATACCC1 enrolled 369 contacts (arising from 308 index notifications), and ATACCC2 enrolled 233 contacts (arising from 163 index notifications) and 19 index cases. SARS-CoV-2 RNA was detected in 163 (26%) of the 621 participants. Whole-genome sequencing of PCR-positive cases confirmed that 71 participants had delta variant infection (18 index cases and 53 contacts), 42 had alpha variant infection (one index case and 41 contacts), and 50 had pre-alpha variant infection (all contacts; figure 1A).

Of 163 PCR-positive participants, 89 (55%) were female and 133 (82%) were White. Median age was 36 years (IQR 26–50). Sex, age, ethnicity, body-mass index (BMI) distribution, and the frequency of comorbidities were similar among those with delta, alpha, and pre-alpha infection, and for vaccinated and unvaccinated delta-infected participants, except for age and sex (appendix pp 2–3). There were fewer unvaccinated females than males (p=0·04) and, as expected from the age-prioritisation of the UK vaccine roll-out, unvaccinated participants infected with the delta variant were significantly younger (p<0·001; appendix p 3). Median time between exposure to the index case and study enrolment was 4 days (IQR 4–5). All participants had non-severe ambulatory illness or were asymptomatic. The proportion of asymptomatic cases did not differ among fully vaccinated, partially vaccinated, and unvaccinated delta groups (appendix p 3).

	Total	PCR positive	PCR negative	SAR (95% CI)	p value
Contacts					
All	231	53	178	23 (18–29)	NA
Fully vaccinated	140	31	109	22 (16–30)	0·16
Unvaccinated	44	15	29	34 (22–49)	..
Partially vaccinated	47	7	40	15 (7–28)	NA
Household contacts					
All	205	53	152	26 (20–32)	NA
Fully vaccinated	126	31	95	25 (18–33)	0·17
Unvaccinated	40	15	25	38 (24–53)	..
Partially vaccinated	39	7	32	18 (9–33)	NA

χ^2 test was performed to calculate p values for differences in SAR between fully vaccinated and unvaccinated cases. One PCR-negative contact who withdrew from the study without vaccination status information was excluded. NA=not applicable. SAR=secondary attack rate.

Table 1: **SAR in contacts of delta-exposed index cases recruited to the ATACCC2 study**

No pre-alpha-infected and only one alpha-infected participant had received a COVID-19 vaccine before study enrolment. Of 71 delta-infected participants (of whom 18 were index cases), 23 (32%) were unvaccinated, ten (14%) were partially vaccinated, and 38 (54%) were fully vaccinated (figure 1A; appendix p 3). Of the 38 fully vaccinated delta-infected participants, 14 had received the BNT162b2 mRNA vaccine (Pfizer–BioNTech), 23 the ChAdOx1 nCoV-19 adenovirus vector vaccine (Oxford–AstraZeneca), and one the CoronaVac inactivated whole-virion vaccine (Sinovac).

It is highly probable that all but one of the 233 ATACCC2 contacts were exposed to the delta variant because they were recruited when the regional prevalence of delta was at least 90%, and mostly 95–99% (figure 1B).[10] Of these, 206 (89%) were household contacts (in 127 households), and 26 (11%) were non-household contacts. Distributions of age, ethnicity, BMI, smoking status, and comorbidities were similar between PCR-positive and PCR-negative contacts (appendix p 4). The median time between second vaccine dose and study recruitment in fully vaccinated contacts with delta variant infection was 74 days (IQR 35–105; range 16–201), and this was significantly longer in PCR-positive contacts than in PCR-negative contacts (101 days [IQR 74–120] *vs* 64 days [32–97], respectively, p=0·001; appendix p 4). All 53 PCR-positive contacts were exposed in household settings and the SAR for all delta variant-exposed household contacts was 26% (95% CI 20–32). SAR was

	All household contacts (n=204)*	Fully vaccinated contacts (n=125)		Partially vaccinated contacts (n=39)		Unvaccinated contacts (n=40)	
		PCR positive (n=31)	PCR negative (n=94)	PCR positive (n=7)	PCR negative (n=32)	PCR positive (n=15)	PCR negative (n=25)
Fully vaccinated index cases (n=50)	69	12	31	1	8	4	13
Partially vaccinated index cases (n=25)	35	7	12	3	10	3	0
Unvaccinated index cases (n=63)	100	12	51	3	14	8	12

Non-household exposed contacts (n=24, all PCR negative) were excluded. One PCR-negative household contact who withdrew from the study without vaccination status information was excluded. One PCR-negative household contact who could not be linked to their index case was also excluded. *The rows below show the number of contacts exposed to each category of index case.

Table 2: **Comparison of vaccination status of the 138 epidemiologically linked PCR-positive index cases for 204 delta variant-exposed household contacts**

not significantly higher in unvaccinated (38%, 95% CI 24–53) than fully vaccinated (25%, 18–33) household contacts (table 1). We estimated vaccine effectiveness at preventing infection (regardless of symptoms) with delta in the household setting to be 34% (bootstrap 95% CI −15 to 60). Sensitivity analyses using a 14 day threshold for time since second vaccination to study recruitment to denote fully vaccinated did not materially affect our estimates of vaccine effectiveness or SAR (data not shown). Although precision is restricted by the small sample size, this estimate is broadly consistent with vaccine effectiveness estimates for delta variant infection based on larger datasets.[9,16,17]

The vaccination status of 138 epidemiologically linked index cases of 204 delta variant-exposed household contacts was available (figure 1B, table 2). The SAR in household contacts exposed to fully vaccinated index cases was 25% (95% CI 15–35; 17 of 69), which is similar to the SAR in household contacts exposed to unvaccinated index cases (23% [15–31]; 23 of 100; table 2). The 53 PCR-positive contacts arose from household exposure to 39 PCR-positive index cases. Of these index cases who gave rise to secondary transmission, the proportion who were fully vaccinated (15 [38%] of 39) was similar to the proportion who were unvaccinated (16 [41%] of 39). The median number of days from the index cases' second vaccination to the day of recruitment for their respective contacts was 73 days (IQR 38–116). Time interval did not differ between index cases who transmitted infection to their contacts and those who did not (94 days [IQR 62–112] and 63 days [35–117], respectively; p=0·43).

18 of the 163 delta variant-infected index cases that led to contact enrolment were themselves recruited to ATACCC2 and serial URT samples were collected from them, allowing for more detailed virology and genome analyses. For 15 of these, their contacts were also recruited (13 household contacts and two non-household contacts). A corresponding PCR-positive household contact was identified for four of these 15 index cases (figure 1B). Genomic analysis showed that index–contact pairs were infected with the same delta variant sub-lineage in these instances, with one exception (figure 2A). In one household (number 4), an unvaccinated index case transmitted the delta variant to an unvaccinated contact, while another partially vaccinated contact was infected with a different delta sub-lineage (which was probably acquired outside the household). In the other three households (numbers 1–3), fully vaccinated index cases transmitted the delta variant to fully vaccinated household contacts, with high viral load in all cases, and temporal relationships between the viral load kinetics that were consistent with transmission from the index cases to their respective contacts (figure 2B).

Inclusion criteria for the modelling analysis selected 133 participant's viral load RNA trajectories from 163 PCR-positive participants (49 with the pre-alpha variant, 39 alpha, and 45 delta; appendix p 14). Of the 45 delta cases, 29 were fully vaccinated and 16 were unvaccinated; partially vaccinated cases were excluded. Of the 133 included cases, 29 (22%) were incident (ie, PCR negative at enrolment converting to PCR positive subsequently) and 104 (78%) were prevalent (ie, already PCR positive at enrolment). 15 of the prevalent cases had a clearly resolvable peak viral load. Figure 3 shows modelled viral RNA (ORF1ab) trajectories together with the viral RNA copy numbers measured for individual participants. The E-gene equivalent is shown in the appendix (p 2). Estimates derived from E-gene cycle threshold value data (appendix pp 5, 7, 9, 11) were similar to those for ORF1ab.

Although viral kinetics appear visually similar for all four groups of cases, we found quantitative differences in estimated viral growth rates and decline rates (tables 3, 4). Population (group-level) estimates of mean viral load decline rates based on ORF1ab cycle threshold value data varied in the range of 0·69–0·95 $\log_{10}$ units per mL per daxes 4; appendix p 10), indicating that a typical 10-day period was required for viral load to decline from peak to undetectable. A faster decline was seen in the alpha (pp=0·93), unvaccinated delta (pp=0·79), and fully vaccinated delta (pp=0·99) groups than in the pre-alpha group. The mean viral load decline rate of the fully vaccinated delta group was also faster than those of the alpha group (pp=0·84) and the unvaccinated delta group (pp=0·85). The differences in decline rates translate into a difference of about 3 days in the mean duration of the decline phase between the pre-alpha and delta vaccinated groups.

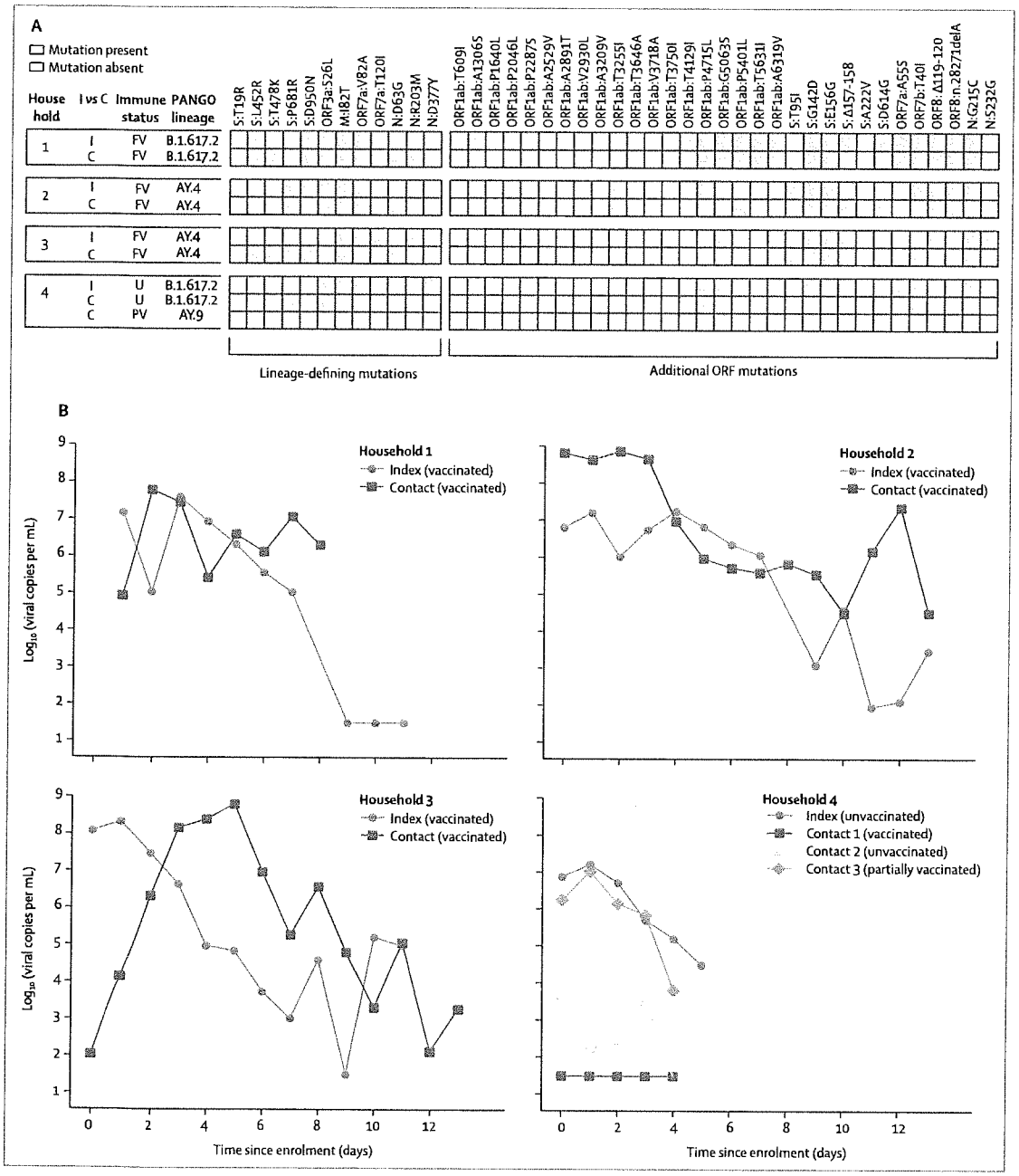
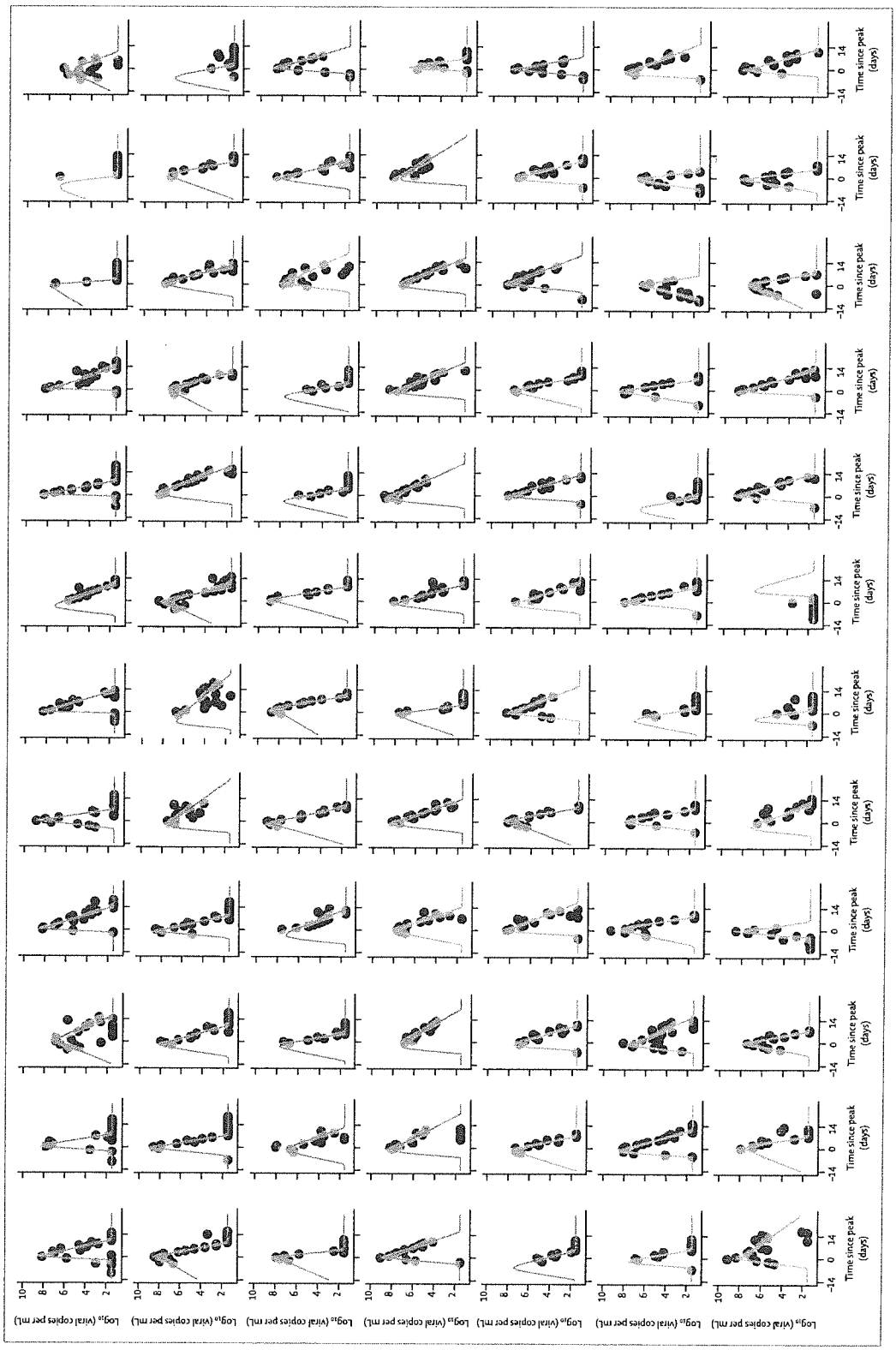


Figure 2: **Virological, epidemiological, and genomic evidence for transmission of the SARS-CoV-2 delta variant (B.1.617.2) in households**
(A) Genomic analysis of the four households with lineage-defining mutations for delta[18] and additional mutations within ORFs displayed to give insight into whether strains from individuals within the household are closely related. Lineages AY.4 and AY.9 are sub-lineages of delta. (B) Viral trajectories and vaccination status of the four index cases infected with the delta variant for whom infection was detected in their epidemiologically linked household contacts. All individuals had non-severe disease. Each plot shows an index case and their household contacts. Undetectable viral load measurements are plotted at the limit of detection ($10^{1\cdot49}$). C=contact. I=index case. FV=fully vaccinated. ORF=open reading frame. PV=partially vaccinated. U=unvaccinated.

Viral load growth rates were substantially faster than decline rates, varying in the range of 2·69–3·24 $\log_{10}$ units per mL per day between groups, indicating that a typical 3-day period was required for viral load to grow from undetectable to peak. Our power to infer differences in growth rates between groups was more restricted than for viral decline, but there was moderate evidence (pp=0·79) that growth rates were lower for



(Figure 3 continues on next page)

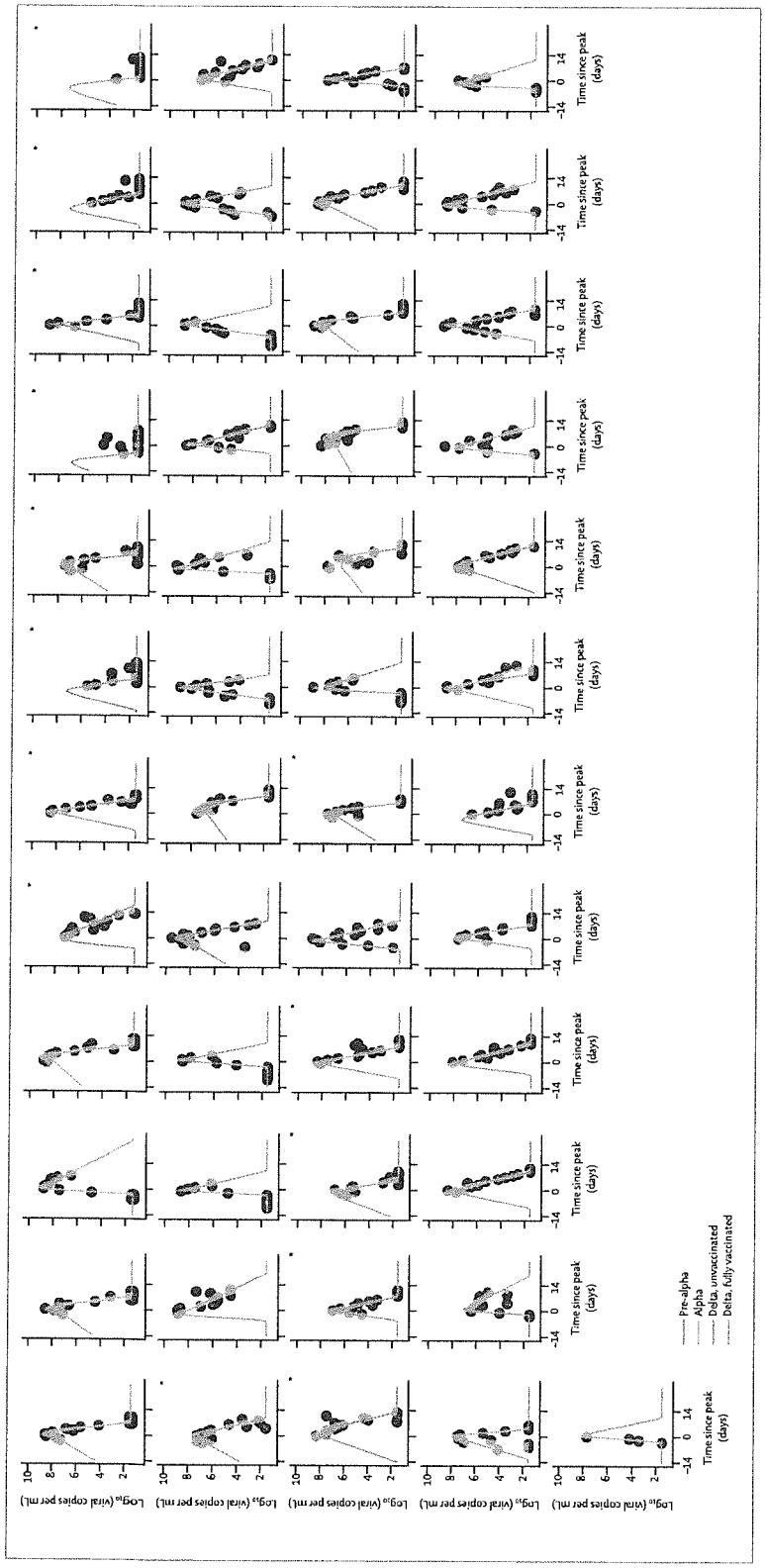


Figure 3: **ORF1ab viral load trajectories from 14 days before to 28 days after peak for 133 participants infected with pre-alpha or alpha variants (unvaccinated), or the delta variant (vaccinated and unvaccinated) variants**
Black circles are measured values, with the first datapoint for each participant being taken to the day of enrolment. Plots are rooted on the day of peak viral load for each participant, denoted as day 0 on the x-axis. Curves show the model posterior median estimate, with a 95% credible interval shading. 133 infected participants, comprising 114 contacts and 19 index cases. *Index cases.

	VL growth rate (95% CrI), log_{10} units per day	Posterior probability estimate is less than pre-alpha	Posterior probability estimate is less than alpha	Posterior probability estimate is less than delta (unvaccinated)	Posterior probability estimate is less than delta (fully vaccinated)
Pre-alpha (n=49)	3·24 (1·78–6·14)	..	0·44	0·27	0·21
Alpha (n=39)	3·13 (1·76–5·94)	0·56	..	0·32	0·25
Delta, unvaccinated (n=16)	2·81 (1·47–5·47)	0·73	0·68	..	0·44
Delta, fully vaccinated (n=29)	2·69 (1·51–5·17)	0·79	0·75	0·56	..

VL growth rates are shown as within-sample posterior mean estimates. Remaining columns show population (group-level) posterior probabilities that the estimate on that row is less than an estimate for a different group. Posterior probabilities are derived from 20 000 posterior samples and have sampling errors of <0·01. VL=viral load. CrI=credible interval.

Table 3: **Estimates of VL growth rates for pre-alpha, alpha, and delta (unvaccinated and fully vaccinated) cases, derived from ORF1ab cycle threshold data**

	VL decline rate (95% CrI), log_{10} units per day	Posterior probability estimate is larger than pre-alpha	Posterior probability estimate is larger than alpha	Posterior probability estimate is larger than delta (unvaccinated)	Posterior probability estimate is larger than delta (fully vaccinated)
Pre-alpha (n=49)	0·69 (0·58–0·81)	..	0·07	0·21	0·01
Alpha (n=39)	0·82 (0·67–1·01)	0·93	..	0·60	0·16
Delta, unvaccinated (n=16)	0·79 (0·59–1·04)	0·79	0·40	..	0·15
Delta, fully vaccinated (n=29)	0·95 (0·76–1·18)	0·99	0·84	0·85	..

VL decline rates are shown as within-sample posterior mean estimates. Remaining columns show population (group-level) posterior probabilities that the estimate on that row is less than an estimate for a different group. Posterior probabilities are derived from 20 000 posterior samples and have sampling errors of <0·01. VL=viral load. CrI=credible interval.

Table 4: **Estimates of VL decline rates for pre-alpha, alpha, and delta (unvaccinated and fully vaccinated) cases, derived from ORF1ab cycle threshold data**

those in the vaccinated delta group than in the pre-alpha group.

We estimated mean peak viral load for 50-year-old adults to be 8·14 (95% CrI 7·95 to 8·32) log_{10} copies per mL, but peak viral load did not differ by variant or vaccination status. However, we estimated that peak viral load increases with age (pp=0·96 that the slope of peak viral load with log[age] was >0), with an estimated slope of 0·24 (95% CrI −0·02 to 0·49) log_{10} copies per mL per unit change in log(age). This estimate translates to a difference of 0·39 (−0·03 to 0·79) in mean peak log_{10} copies per mL between those aged 10 years and 50 years.

Within-group individual participant estimates of viral load growth rate were positively correlated with peak viral load, with a correlation coefficient estimate of 0·42 (95% CrI 0·13 to 0·65; appendix p 8). Hence, individuals with faster viral load growth tend to have higher peak viral load. The decline rate of viral load was also negatively correlated with viral load growth rate, with a correlation coefficient estimate of −0·44 (95% CrI −0·67 to −0·18), illustrating that individuals with faster viral load growth tend to experience slower viral load decline.

Discussion

Households are the site of most SARS-CoV-2 transmission globally.[19] In our cohort of densely sampled household contacts exposed to the delta variant, SAR was 38% in unvaccinated contacts and 25% in fully vaccinated contacts. This finding is consistent with the known protective effect of COVID-19 vaccination against infection.[8,9] Notwithstanding, these findings indicate continued risk of infection in household contacts despite vaccination. Our estimate of SAR is higher than that reported in fully vaccinated household contacts exposed before the emergence of the delta variant.[1,20,21] The time interval between vaccination and study recruitment was significantly higher in fully vaccinated PCR-positive contacts than fully vaccinated PCR-negative contacts, suggesting that susceptibility to infection increases with time as soon as 2–3 months after vaccination—consistent with waning protective immunity. This potentially important observation is consistent with recent large-scale data and requires further investigation.[17] Household SAR for delta infection, regardless of vaccination status, was 26% (95% CI 20–32), which is higher than estimates of UK national surveillance data (10·8% [10·7–10·9]).[10] However, we sampled contacts daily, regardless of symptomatology, to actively identify infection with high sensitivity. By contrast, symptom-based, single-timepoint surveillance testing probably underestimates the true SAR, and potentially also overestimates vaccine effectiveness against infection.

We identified similar SAR (25%) in household contacts exposed to fully vaccinated index cases as in those exposed to unvaccinated index cases (23%). This finding indicates that breakthrough infections in fully vaccinated people can efficiently transmit infection in the household setting. We identified 12 household transmission events between fully vaccinated index case–contact pairs; for three of these, genomic sequencing confirmed that the index case and

contact were infected by the same delta variant sub-lineage, thus substantiating epidemiological data and temporal relationships of viral load kinetics to provide definitive evidence for secondary transmission. To our knowledge, one other study has reported that transmission of the delta variant between fully vaccinated people was a point-source nosocomial outbreak—a single health-care worker with a particular delta variant sub-lineage in Vietnam.[22]

Daily longitudinal sampling of cases from early (median 4 days) after exposure for up to 20 days allowed us to generate high-resolution trajectories of URT viral load over the course of infection. To date, two studies have sequentially sampled community cases of mild SARS-CoV-2 infection, and these were from highly specific population groups identified through asymptomatic screening programmes (eg, for university staff and students[23] and for professional athletes[24]).

Our most predictive model of viral load kinetics estimated mean peak $\log_{10}$ viral load per mL of 8·14 (95% CrI 7·95–8·32) for adults aged 50 years, which is very similar to the estimate from a 2021 study using routine surveillance data.[25] We found no evidence of variation in peak viral load by variant or vaccination status, but we report some evidence of modest but significant (pp=0·95) increases in peak viral load with age. Previous studies of viral load in children and adults[4,25,26] have not used such dense sequential sampling of viral load and have, therefore, been restricted in their power to resolve age-related differences; the largest such study[25] reported a similar difference between children and adults to the one we estimated. We found the rate of viral load decline was faster for vaccinated individuals with delta infection than all other groups, and was faster for individuals in the alpha and unvaccinated delta groups than those with pre-alpha infection.

For all variant vaccination groups, the variation between participants seen in viral load kinetic parameter estimates was substantially larger than the variation in mean parameters estimated between groups. The modest scale of differences in viral kinetics between fully vaccinated and unvaccinated individuals with delta infection might explain the relatively high rates of transmission seen from vaccinated delta index cases in our study. We found no evidence of lower SARs from fully vaccinated delta index cases than from unvaccinated ones. However, given that index cases were identified through routine symptomatic surveillance, there might have been a selection bias towards identifying untypically symptomatic vaccine breakthrough index cases.

The differences in viral kinetics we found between the pre-alpha, alpha, and delta variant groups suggest some incremental, but potentially adaptive, changes in viral dynamics associated with the evolution of SARS-CoV-2 towards more rapid viral clearance. Our study provides the first evidence that, within each variant or vaccination group, viral growth rate is positively correlated with peak viral load, but is negatively correlated with viral decline rate. This finding suggests that individual infections during which viral replication is initially fastest generate the highest peak viral load and see the slowest viral clearance, with the latter not just being due to the higher peak. Mechanistically, these data suggest that the host and viral factors determining the initial growth rate of SARS-CoV-2 have a fundamental effect on the trajectory throughout infection, with faster replication being more difficult (in terms of both peak viral load and the subsequent decline of viral load) for the immune response to control. Analysis of sequentially sampled immune markers during infection might give insight into the immune correlates of these early differences in infection kinetics. It is also possible that individuals with the fastest viral load growth and highest peaks contribute disproportionately to community transmission, a hypothesis that should be tested in future studies.

Several population-level, single-timepoint sampling studies using routinely available data have found no major differences in cycle threshold values between vaccinated and unvaccinated individuals with delta variant infection.[10,27,28] However, as the timepoint of sampling in the viral trajectory is unknown, this restricts the interpretation of such results. Two other studies longitudinally sampled vaccinated and unvaccinated individuals with delta variant infection.[23,29] A retrospective cohort of hospitalised patients in Singapore[29] also described a faster rate of viral decline in vaccinated versus unvaccinated individuals with delta variant, reporting somewhat larger differences in decline rates than we estimated here. However, this disparity might be accounted for by the higher severity of illness in unvaccinated individuals in the Singaporean study (almost two-thirds having pneumonia, one-third requiring COVID-19 treatment, and a fifth needing oxygen) than in our study, given that longer viral shedding has been reported in patients with more severe illness.[10] A longitudinal sampling study in the USA reported that pre-alpha, alpha, and delta variant infections had similar viral trajectories.[24] The study also compared trajectories in vaccinated and unvaccinated individuals, reporting similar proliferation phases and peak cycle threshold values, but more rapid clearance of virus in vaccinated individuals. However, this study in the USA stratified by vaccination status and variant separately, rather than jointly, meaning vaccinated individuals with delta infection were being compared with, predominantly, unvaccinated individuals with pre-alpha and alpha infection. Moreover, sampling was done as part of a professional sports player occupational health screening programme, making the results not necessarily representative of typical community infections.

Our study has limitations. First, we recruited only contacts of symptomatic index cases as our study recruitment is derived from routine contact-tracing notifications. Second, index cases were defined as the first household member to have a PCR-positive swab, but we cannot exclude the possibility that another household member might already have been infected and transmitted

to the index case. Third, recording of viral load trajectories is subject to left censoring, where the growth phase in prevalent contacts (already PCR-positive at enrolment) was missed for a proportion of participants. However, we captured 29 incident cases and 15 additional cases on the upslope of the viral trajectory, providing valuable, informative data on viral growth rates and peak viral load in a subset of participants. Fourth, owing to the age-stratified rollout of the UK vaccination programme, the age of the unvaccinated, delta variant-infected participants was lower than that of vaccinated participants. Thus, age might be a confounding factor in our results and, as discussed, peak viral load was associated with age. However, it is unlikely that the higher SAR observed in the unvaccinated contacts would have been driven by younger age rather than the absence of vaccination and, to our knowledge, there is no published evidence showing increased susceptibility to SARS-CoV-2 infection with decreasing age.[11] Finally, although we did not perform viral culture here—which is a better proxy for infectiousness than RT-PCR—two other studies[27,32] have shown cultivable virus from around two-thirds of vaccinated individuals infected with the delta variant, consistent with our conclusions that vaccinated individuals still have the potential to infect others, particularly early after infection when viral loads are high and most transmission is thought to occur.[30]

Our findings help to explain how and why the delta variant is being transmitted so effectively in populations with high vaccine coverage. Although current vaccines remain effective at preventing severe disease and deaths from COVID-19, our findings suggest that vaccination alone is not sufficient to prevent all transmission of the delta variant in the household setting, where exposure is close and prolonged. Increasing population immunity via booster programmes and vaccination of teenagers will help to increase the currently limited effect of vaccination on transmission, but our analysis suggests that direct protection of individuals at risk of severe outcomes, via vaccination and non-pharmacological interventions, will remain central to containing the burden of disease caused by the delta variant.

Contributors

AS, JD, MZ, NMF, WB, and ALal conceptualised the study. AS, SH, JD, KJM, AK, JLB, MGW, ND-F, RV, RK, JF, CT, AVK, JC, VQ, EC, JSN, SH, EM, TP, HH, CL, JS, SB, JP, CA, SA, and NMF were responsible for data curation and investigation. AS, SH, KJM, JLB, AC, NMF, and ALal did the formal data analysis. MAC, AB, DJ, SM, JE, PSF, SD, and ALac did the laboratory work. RV, RK, JF, CT, AVK, JC, VQ, EC, JSN, SH, EM, and SE oversaw the project. AS, SH, JD, KJM, JLB, NMF, and ALal accessed and verified the data. JD, MZ, and ALal acquired funding. NMF sourced and oversaw the software. AS and ALal wrote the initial draft of the manuscript. AS, JD, GPT, MZ, NMF, SH, and ALal reviewed and edited the manuscript. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

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Declaration of interests

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Data sharing

An anonymised, de-identified version of the dataset can be made available upon request to allow all results to be reproduced. Modelling code will also be made publicly available on the GitHub repository.

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The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Population Immunity and Covid-19 Severity with Omicron Variant in South Africa

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Abstract

BACKGROUND

The B.1.1.529 (omicron) variant of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) was first identified on November 25, 2021, in Gauteng province, South Africa. Data regarding the seroprevalence of SARS-CoV-2 IgG in Gauteng before the fourth wave of coronavirus disease 2019 (Covid-19), in which the omicron variant was dominant, are needed.

METHODS

We conducted a seroepidemiologic survey from October 22 to December 9, 2021, in Gauteng to determine the seroprevalence of SARS-CoV-2 IgG. Households included in a previous seroepidemiologic survey (conducted from November 2020 to January 2021) were contacted; to account for changes in the survey population, there was a 10% increase in the households contacted, with the use of the same sampling framework. Dried-blood-spot samples were tested for IgG against SARS-CoV-2 spike protein and nucleocapsid protein with the use of quantitative assays. We also evaluated Covid-19 epidemiologic

trends in Gauteng, including cases, hospitalizations, recorded deaths, and excess deaths from the start of the pandemic through January 12, 2022.

RESULTS

Samples were obtained from 7010 participants, of whom 1319 (18.8%) had received a Covid-19 vaccine. The seroprevalence of SARS-CoV-2 IgG ranged from 56.2% (95% confidence interval [CI], 52.6 to 59.7) among children younger than 12 years of age to 79.7% (95% CI, 77.6 to 81.5) among adults older than 50 years of age. Vaccinated participants were more likely to be seropositive for SARS-CoV-2 than unvaccinated participants (93.1% vs. 68.4%). Epidemiologic data showed that the incidence of SARS-CoV-2 infection increased and subsequently declined more rapidly during the fourth wave than it had during the three previous waves. The incidence of infection was decoupled from the incidences of hospitalization, recorded death, and excess death during the fourth wave, as compared with the proportions seen during previous waves.

CONCLUSIONS

Widespread underlying SARS-CoV-2 seropositivity was observed in Gauteng before the omicron-dominant wave of Covid-19. Epidemiologic data showed a decoupling of hospitalizations and deaths from infections while omicron was circulating. (Funded by the Bill and Melinda Gates Foundation.)

Introduction

The B.1.1.529 (omicron) variant of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) was first identified on November 25, 2021, in Gauteng province, South Africa.[1] The World Health Organization designated omicron as a variant of concern because of its predicted high transmissibility and its potential to evade immunity from neutralizing antibodies induced by vaccination or natural infection with wild-type virus.[2] The omicron variant contains mutations that indicate that it could be more infectious, more transmissible, and possibly better able to evade innate immunity and neutralizing antibody activity than wild-type virus.[3-5] In addition to having at least 32 mutations affecting the spike protein,[6] the omicron variant harbors 3 mutations involving the membrane protein and 6 involving the nucleocapsid protein, whereas the antibody-evasive B.1.351 (beta) variant has only 7 spike-protein mutations and 1 nucleocapsid-protein mutation.[7]

The omicron variant outcompeted the B.1.617.2 (delta) variant in Gauteng and was responsible for 98.4% of new cases sequenced in South Africa in December 2021.[8] This fourth wave of coronavirus disease 2019 (Covid-19) arose in the context of the rollout of Covid-19 vaccines, which began on May 17, 2021, in South Africa. We previously conducted a population-wide seroepidemiologic survey in Gauteng that was completed on January 22, 2021.[9] We found that 19.1% of the population was seropositive for SARS-CoV-2, as assessed by the detection of IgG against the receptor-binding domain; the seroprevalence ranged from 5% to 43% across provincial subdistricts.[9] After that survey was completed, South Africa faced a third wave of Covid-19, from approximately April 7 to November 1, that was largely due to the delta variant, which outcompeted the beta variant.[10]

We report the results of a follow-up seroepidemiologic survey in Gauteng that was completed on December 9, 2021, and thus provides seroprevalence data largely from before the fourth wave of Covid-19. Furthermore, we report data regarding Covid-19 epidemiologic trends in Gauteng, including cases, hospitalizations, recorded deaths, and excess deaths from the start of the pandemic through January 12, 2022.

Methods

STUDY SETTING

Gauteng is divided into five health districts (Johannesburg, Ekurhuleni, Sedibeng, Tshwane, and West Rand) that comprise 26 subdistricts.[11] Gauteng constitutes 1.5% of the landmass in South Africa but contains 26% of the population (15.5 of 59.6 million persons).[11] The overall population density in Gauteng is 737 persons per square kilometer, with the value ranging from 3400 in Johannesburg, where 36.9% of the population lives, to 200 in West Rand, where 6.2% of the population lives (Table S1 in the **Supplementary Appendix**, available with the full text of this article at NEJM.org).

STUDY SURVEY

This survey included the same households that were sampled during our previous survey, which was undertaken from November 4, 2020, to January 22, 2021.[9] The previous survey was started 9 weeks after the onset of the second wave of Covid-19 in Gauteng, which was dominated by the beta variant. Details regarding the previous survey, including the sampling framework used, have been published[9] and are summarized in the Supplementary Methods section of the **Supplementary Appendix**.

This survey was conducted from October 22 to December 9, 2021. To account for possible nonparticipation, out-migration, and death since the previous survey, there was a 10% increase in the households that were sampled; the additional households were sampled in the same clusters used previously. The survey was powered to evaluate seropositivity for SARS-CoV-2 at the district and subdistrict levels. Demographic and epidemiologic data were collected with the use of an electronic questionnaire.[9] Details regarding the questionnaire are provided in the **Supplementary Appendix**.

The Human Research Ethics Committee at the University of the Witwatersrand granted a waiver for ethics approval of the survey, which was performed at the behest of the Gauteng Department of Health as part of public health surveillance. Nevertheless, all participants provided written informed consent; those who were approached to participate were free to decline participation. The authors designed the study, collected and analyzed the data, and vouch for the completeness and accuracy of the data and the fidelity of the study to the protocol. The authors wrote the manuscript; no one who is not an author contributed to the writing of the manuscript.

SEROLOGIC ANALYSIS

Dried-blood-spot samples were obtained from participants and tested for IgG against SARS-CoV-2 spike protein and nucleocapsid protein with the use of quantitative assays on the Luminex platform. Anti-nucleocapsid IgG was included to identify persons who were seropositive from natural infection rather

than vaccination. Details regarding the serologic assays have been published[12,13] and are summarized in the Supplementary Appendix.

COVID-19 DATA SOURCES

Data regarding daily cases, hospitalizations, and recorded deaths were sourced from the South African National Institute for Communicable Diseases daily databases, including the DATCOV database, through January 12, 2022.[14,15] Data regarding weekly excess deaths attributable to Covid-19 were defined by and sourced from the South African Medical Research Council through January 8, 2022.[16] We analyzed these epidemiologic data for Gauteng and its five health districts, both overall and with stratification according to age group and sex when granular data were available.

Cases included asymptomatic and symptomatic infections with SARS-CoV-2 confirmed by either a nucleic acid amplification assay or a rapid antigen test. Hospitalizations included admissions for SARS-CoV-2 infection, as well as admissions for other illnesses in which SARS-CoV-2 infection was incidentally identified on routine screening at the time of admission. Definitions of recorded death and excess death attributable to Covid-19 are provided in the Supplementary Appendix.

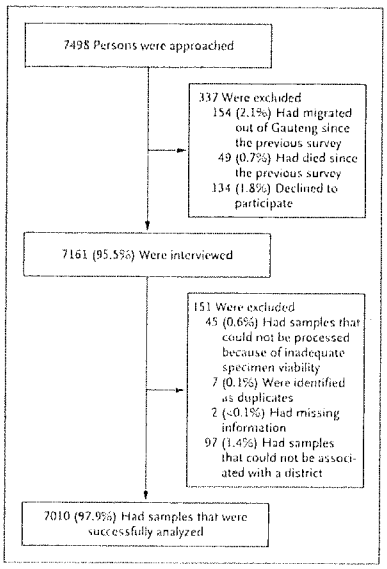
STATISTICAL ANALYSIS

The sample-size justification and the methods for repeated random sampling of households that were used in our previous survey have been published[9] and are summarized in the Supplementary Appendix, together with the methods for analyses of associations with seropositivity, which were performed with the use of generalized linear models with log link to estimate risk ratios. These were unadjusted, univariable analyses for each risk factor. Data regarding daily cases, hospitalizations, and recorded deaths and weekly excess deaths were converted to incidences with the use of population denominators from Statistics South Africa mid-2020 projections for South Africa and its provinces.[11]

Results

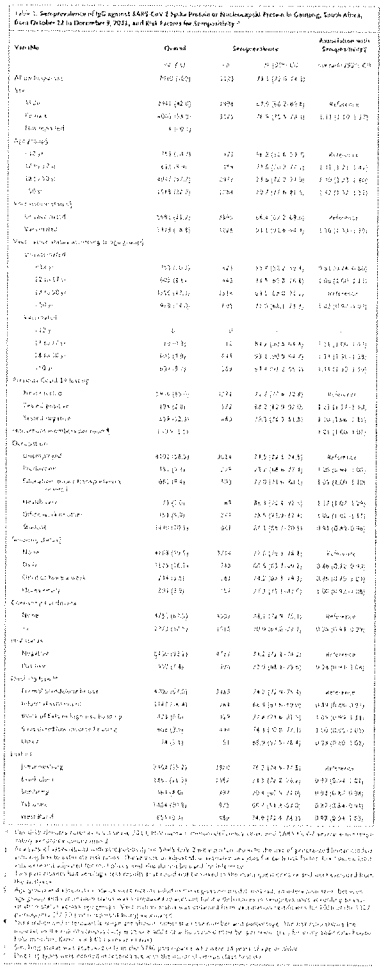
PARTICIPANTS

Figure 1.



Survey Participants.

Table 1.



Seroprevalence of IgG against SARS-CoV-2 Spike Protein or Nucleocapsid Protein in Gauteng, South Africa, from October 22 to December 9, 2021, and Risk Factors for Seropositivity.

We obtained samples that were adequate for serostatus evaluation from 7010 of 7498 participants from 3047 households (**Figure 1**); 83% of the samples had been obtained by November 25, 2021, when the

omicron variant was first identified (Fig. S1). Demographic and household characteristics, known underlying medical conditions and participant-reported human immunodeficiency virus status, and vaccination status of the survey participants are shown in **Table 1**. The degree to which the survey population was representative of the general population of Gauteng and of South Africa is described in Table S2. Vaccination in Gauteng according to district, age, and vaccine is summarized in Table S3. As of November 25, 2021, of the total population of 12,191,569 persons 12 years of age or older (who were eligible for vaccination), 4,386,646 (36.0%) had received at least one dose of BNT162b2 or Ad26.COV2.S, and 2,452,017 (20.1%) had received two doses. Of the 2,416,045 persons older than 50 years of age, 1,074,303 (44.5%) had received two doses of BNT162b2.

SEROPREVALENCE

Among unvaccinated participants, the overall prevalence of anti-spike or anti-nucleocapsid IgG seropositivity was 68.4% (95% confidence interval [CI], 67.2 to 69.6), whereas the prevalence of anti-nucleocapsid IgG seropositivity was 39.7% (95% CI, 38.4 to 41.0), a finding that indicates a lack of sensitivity of anti-nucleocapsid IgG for the detection of previous infection. We thus focused on the overall prevalence of anti-spike or anti-nucleocapsid IgG seropositivity.

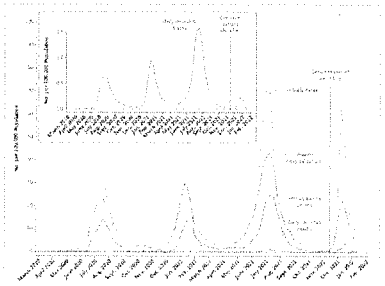
Among all participants, the overall seroprevalence was 73.1% (95% CI, 72.0 to 74.1) (**Table 1**). The seroprevalence was heterogeneous across provincial districts, ranging from 66.7% (95% CI, 54.2 to 69.0) in Tshwane, where the omicron variant was first identified, to 76.2% (95% CI, 74.5 to 77.8) in Johannesburg (Fig. S2). In addition, the seroprevalence was heterogeneous across subdistricts, ranging from 72.7% to 85.8% within Johannesburg and from 58.9% to 77.4% within Tshwane (Table S4).

Female participants were more likely to be seropositive than male participants (76.9% vs. 67.9%; risk ratio, 1.13; 95% CI, 1.10 to 1.17). The seroprevalence varied according to age group; it was lowest among children younger than 12 years of age (56.2%) and highest among adults older than 50 years of age (79.7%). Children 12 to 17 years of age were more likely to be seropositive than children younger than 12 years of age (73.8% vs. 56.2%; risk ratio, 1.31; 95% CI, 1.21 to 1.42). Participants who had received a Covid-19 vaccine were more likely to be seropositive than unvaccinated participants (93.1% vs. 68.4%; risk ratio, 1.36; 95% CI, 1.33 to 1.39). Among vaccinated participants, the seroprevalence was consistently high across age groups; among adults 18 to 50 years of age, those who were vaccinated had a higher seroprevalence than those who were unvaccinated.

Participants who had previously tested positive for SARS-CoV-2 infection were more likely to be seropositive than participants who had never been tested (88.2% vs. 71.7%; risk ratio, 1.23; 95% CI, 1.17 to 1.30). Participants living in an informal settlement had a lower seroprevalence than participants living in a standalone house (66.3% vs. 74.2%; risk ratio, 0.89; 95% CI, 0.86 to 0.93). Daily smoking was associated with a lower seroprevalence than was not smoking (66.5% vs. 77.6%; risk ratio, 0.86; 95% CI, 0.82 to 0.90).

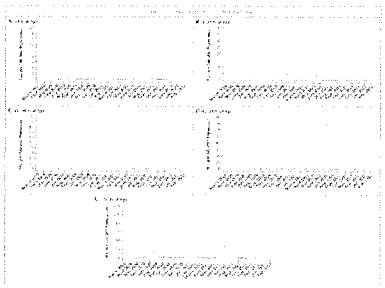
COVID-19 TRENDS

Figure 2.



Cases, Hospitalizations, Recorded Deaths, and Excess Deaths Attributable to Covid-19 in Gauteng, South Africa, from the Start of the Pandemic through January 12, 2022.

Figure 3.

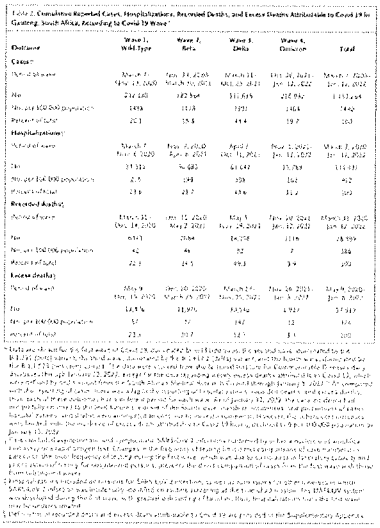


Covid-19 Cases, Hospitalizations, and Recorded Deaths in Gauteng, South Africa, According to Age Group.

Daily cases, weekly hospitalizations, daily recorded deaths, and weekly excess deaths attributable to Covid-19 in Gauteng are shown in **Figure 2**. Daily cases, hospitalizations, and recorded deaths are also shown with stratification according to age group (**Figure 3**) and according to sex (Fig. S3).

During the fourth wave of Covid-19, in which the omicron variant was dominant, the daily case incidence increased more rapidly and also appeared to be decreasing more quickly than it had during the three previous waves (**Figure 2**). The time from the onset to the peak of the wave was 1 month in the fourth wave, as compared with 2 months in the third wave. As of January 12, 2022, the case incidence had not yet fully returned to the level before the onset of the fourth wave, but the wave was nearing its end, on the basis of the trajectory shown in **Figure 2**. At that time, there were almost no recorded or excess deaths attributable to Covid-19 per 100,000 population.

Table 2.



Cumulative Reported Cases, Hospitalizations, Recorded Deaths, and Excess Deaths Attributable to Covid-19 in Gauteng, South Africa, According to Covid-19 Wave.

The number of documented Covid-19 cases in the fourth wave (226,932) was higher than that in the second wave (182,564) and lower than that in the third wave (511,638), whereas the incidences of hospitalization, recorded death, and excess death attributable to Covid-19 in the fourth wave were consistently lower than the incidences in earlier waves (**Table 2**). In addition, the peak incidences of hospitalization, recorded death, and excess death in the fourth wave were lower than the peak incidences in previous waves. The fourth wave contributed 11.2%, 3.9%, and 3.3% of overall hospitalizations, recorded deaths, and excess deaths due to Covid-19, respectively, whereas the third wave, in which the delta variant was dominant, contributed 43.6%, 49.3%, and 52.7%. Similar trends were observed across all districts (Fig. S4). Although there is a lag in the reporting of weekly excess deaths, the incidence in the fourth wave as of January 8, 2022 (12 per 100,000 population), was lower than the incidence in the third wave (197 per 100,000 population). As of January 12, 2022, incidences were on an ongoing downward trajectory, with a 7-day moving average of 7.28 cases, 0.96 hospitalizations, and 0.11 recorded deaths per 100,000 population — a decrease by a factor of 9.3, 3.3, and 2.4 from the peak incidence of 67.56 cases, 3.18 hospitalizations, and 0.26 recorded deaths per 100,000 population, respectively. The incidences were nearing prewave levels (as of October 25, 2021) of 0.46 cases, 0.15 hospitalizations, and 0.04 recorded deaths per 100,000 population.

During the fourth wave, decreased incidences of hospitalization and recorded death were evident across all age groups older than 17 years and among both men and women. The incidences of hospitalization and recorded death among children 17 years of age or younger, which have consistently been markedly lower than the incidences in older age groups, were similar to the incidences during earlier waves, except for a lower mortality among children 5 to 17 years of age during the fourth wave than during the third (delta-dominant) wave (**Figure 3** and Tables S5, S6, and S7).

Discussion

In Gauteng, the resurgence of Covid-19 that was dominated by the omicron variant evolved at a time when Covid-19 vaccine coverage was 36.0% among persons 12 years of age or older, with only 20.1% having received at least two doses of a Covid-19 vaccine as part of the national vaccine rollout program. Nevertheless, the results of our survey showed widespread underlying SARS-CoV-2 seropositivity across the province (73.1%), including a prevalence at the subdistrict level of up to 85.8%, before the onset of the omicron-dominant wave. This high seroprevalence was primarily induced by previous SARS-CoV-2 infection, as evidenced by the 68.4% seroprevalence among participants who had not received a Covid-19 vaccine. The methods used for selecting the random sample of households in the survey, with a distribution proportionate to subdistrict population sizes, ensured that the sample was representative of the general population of Gauteng.

In this context, we observed a dramatic decoupling of hospitalizations and deaths from infections during the fourth wave of Covid-19, as compared with the proportions seen during the three previous waves. The biologic basis for this decoupling could be the extensive cell-mediated immunity in the population that was induced by previous natural infection and vaccination. At least one vaccine dose had been administered to 61.2% of adults older than 50 years of age (1,479,288 of 2,416,045), who had accounted for 81.0% of all deaths (22,269 of 27,500) due to Covid-19 in Gauteng through the end of the third wave.[17] Although we did not evaluate cell-mediated immunity, other studies have shown that natural infection induces a diverse polyepitopic cell-mediated immune response that targets the spike protein, nucleocapsid protein, and membrane protein.[18] Consequently, cell-mediated immunity is likely to be more durable than neutralizing antibody–mediated immunity in the context of small mutations,[19] particularly those mainly affecting the spike protein, such as those in the omicron variant. Furthermore, natural infection induces robust memory T-cell responses, including long-lived cytotoxic (CD8+) T cells, which have a half-life of 125 to 255 days.[20]

We think that the evolution of cell-mediated immunity from previous natural infection and vaccination has resulted in the decoupling of the high case incidence seen with the omicron variant from the incidence of severe disease (hospitalizations and deaths). This decoupling has occurred despite evidence that the omicron variant evades neutralizing antibody activity induced by spike-protein–based vaccines and by previous infection with other variants that did not harbor the same full set of putatively antibody-evasive mutations. Our hypothesis is supported by two recent preprint publications, which indicated that most of the T-cell response induced by vaccination or natural infection cross-recognizes the omicron variant, thereby probably contributing to protection against severe disease.[21,22] An alternative or additional mechanism by which protection against severe disease may be conferred, despite the reduced neutralizing antibody activity against the omicron variant, is through Fc-mediated effector functions of non-neutralizing antibodies that induce antibody-mediated cellular phagocytosis, complement deposition, and natural killer–cell activation.[19,23] In addition, the omicron variant may be less potent in causing serious illness.

We saw a high incidence of Covid-19 cases due to the omicron variant despite the high seroprevalence of humoral immune responses, a finding consistent with the antibody-evasive nature of the omicron variant. Reports have indicated that the omicron variant is more capable of evading neutralizing antibody activity than even the beta variant.[7,24-26] Neutralizing antibody activity against the omicron

variant after two doses of BNT162b2 or AZD1222 (also known as ChAdOx1 nCoV-19) was shown to be substantially lower than vaccine-induced neutralizing antibody activity against wild-type virus.[27,28] Nevertheless, the majority of persons with hybrid immunity from natural infection and BNT162b2 or AZD1222 vaccination have measurable neutralizing antibody activity against the omicron variant, albeit a lower level than that against the wild-type virus.[24] In this context, a high incidence of breakthrough cases and reinfections with the omicron variant was to be expected in South Africa, where the majority of persons had immunity from natural infection, which induces a lower magnitude of anti-spike neutralizing and binding antibody responses than vaccination.[25] Furthermore, as part of its vaccine rollout at the time of the evolution of the fourth wave, South Africa was providing only a single dose of Ad26.COV2.S, which induces lower titers of neutralizing and blocking antibodies than two doses of BNT162b2[25]; the third (booster) dose of BNT162b2 had not been introduced in South Africa at that time.

This clinical evidence of the antibody-evasive nature of the omicron variant is corroborated by early studies that showed limited vaccine effectiveness against omicron at 25 weeks after two doses of AZD1222 or BNT162b2.[29] However, vaccine effectiveness was substantially increased at 2 weeks after a booster dose of BNT162b2,[29] which results in much higher neutralizing antibody titers than two doses of the vaccine[30] and thus may partly mitigate the relative antibody-evasiveness of the omicron variant. In addition, in South Africa, vaccine effectiveness against hospitalization was 70% with the omicron variant, as compared with 93% with the delta variant.[31] These data, together with the very limited neutralizing antibody activity against the omicron variant after two doses of AZD1222 or BNT162b2, further corroborate the evidence that protection against severe Covid-19 due to the omicron variant is probably mediated by much lower neutralizing antibody titers than those required to protect against SARS-CoV-2 infection or mild Covid-19[25] or is provided by cell-mediated immunity or the Fc-effector functions of non-neutralizing antibodies (or a combination of these mechanisms).[19,23]

The antibody-evasive nature of the omicron variant is analogous to the antibody-evasiveness of the beta variant in recipients of AZD1222, the AstraZeneca chimpanzee adenovirus–based vaccine. AZD1222 was shown to have no effectiveness against mild-to-moderate Covid-19 due to the beta variant.[32] However, vaccine effectiveness against hospitalization or death due to the beta or P.1 (gamma) variant was 80% in a report from Canada.[33] Although AZD1222 induced nominal neutralizing antibody activity against the beta variant, only 11 of the 87 spike-protein epitopes targeted by T-cell immune responses induced by AZD1222 were affected by mutations in the beta variant.[32] The dissociation between the lack of AZD1222-induced neutralizing antibody activity and the protection against severe disease involving the lower respiratory tract was also observed in a challenge study with AZD1222 against the beta variant in a Syrian golden hamster model.[34]

Evidence of the high transmissibility of the omicron variant is corroborated by the rapid rise in reported Covid-19 cases in Gauteng during the fourth wave. Indeed, the increase in the case incidence during the fourth wave occurred faster than that during any previous wave, a finding that indicates that the omicron variant is more transmissible than even the delta variant, which had an estimated reproductive number (R_O) of 5 to 6.[35]

Our study has some limitations. First, we used publicly available data regarding Covid-19 morbidity and mortality that were collated in surveillance systems and could have changed over time, which could affect comparisons across the four waves. The DATCOV database does not distinguish between patients hospitalized for SARS-CoV-2 infection and patients hospitalized for other illnesses who incidentally had a positive test for SARS-CoV-2 on routine screening. Nevertheless, data from these systems are unlikely to have changed since the third wave. Second, changes in the frequency of testing over time limit head-to-head comparisons of case numbers across waves, although the criteria for testing have been similar since the start of the second wave. Finally, the fourth wave had not fully subsided at the time of this analysis. The numbers, incidences, and proportions of total cumulative cases, hospitalizations, and deaths attributable to this wave — in particular, the data for hospitalizations and deaths, because there is a lag in the reporting of these data — were anticipated to continue to increase somewhat. However, the subsequent increases were limited, with the incidence of excess death attributable to Covid-19 having declined to 0 per 100,000 population by January 15, 2022.

Our hypothesis that cell-mediated immunity primarily due to natural infection, with or without Covid-19 vaccination, has resulted in the decoupling of cases from severe disease remains to be investigated. In particular, the extent to which the polyepitopic T-cell response induced by vaccination against the spike protein — as well as the even more diverse polyepitopic T-cell response stimulated by natural infection, with or without vaccination — remains cross-reactive against the omicron variant warrants further investigation.[21,22] Another possible contributing factor to the decoupling of cases from severe disease with the omicron variant, as compared with the proportions seen with previous variants, is that the omicron variant may be more adept at infecting the upper airways and less adept at infecting the lower airways, which could result in reduced virulence.[36] The difference in the prevalence of immunity across waves limits our ability to draw any conclusions regarding the relative roles of reduced virulence and higher prevalence of underlying cell-mediated immunity in contributing to the decoupling of cases from severe disease observed with the omicron variant in our study.

We think that the decoupling of the incidence of Covid-19 cases from the incidences of hospitalization and death during the omicron-dominant wave in South Africa heralds a turning point in the Covid-19 pandemic, if the primary goal is protection against severe disease and death rather than prevention of infection. The 70% vaccine effectiveness against severe disease with BNT162b2 in South Africa[31] might well be due to the hybrid cell-mediated immunity induced by vaccination and natural infection. Whether the same protection against severe Covid-19 due to the omicron variant will be seen in countries in which immunity is mainly from vaccination remains to be determined.

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Data are available at www.wits-vida.org; requests for data sharing should be directed to Dr. Madhi at shabir.madhi@wits.ac.za.

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Supplementary Material

Supplementary Appendix	PDF	1557KB
Disclosure Forms	PDF	299KB

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SUBJECT: PROVISION OF BOOSTER DOSES OF COVID VACCINES

1. From 24th December 2021, **individuals older than 18 years of age** who have received one dose of the **Janssen® Covid (J&J) vaccine** will be **eligible to receive a booster dose of the Janssen® vaccine after an interval of two months (60 days).**

    1.1. The recommended interval between the previous and the booster dose of the Janssen® vaccine is **two months (60 days)**. Whilst the booster dose should preferably be given within six months of the previous dose, there is no upper limit to the interval i.e. the booster dose can be given more than six months after the first dose.

    1.2. In practice this means that anyone who received one dose of the Janssen® vaccine on or before the 24th October 2021, will immediately be eligible to receive a booster dose of the Janssen® vaccine. Additional individuals will sequentially become eligible once the interval of 60 days has elapsed.

    1.3. Immunocompromised individuals who have received an additional dose of the Janssen® vaccine will become eligible to receive a booster dose 60 days after receiving the additional dose.

2. From 28th December 2021, **individuals over the age of 18 years who have received two doses of the Pfizer Cominarty® vaccine** will be eligible to receive **a booster dose of the Cominarty® vaccine after an interval of six months (180 days).**

    2.1. The recommended interval between an individual receiving their second dose of the Cominarty® vaccine, and the booster dose is six months (180 days). However, there is no upper limit to the interval i.e. the booster dose can be given more than 180 days after the second dose.

    2.2. The first people to receive their second dose of Cominarty® vaccine as part of the vaccine roll-out will become eligible to receive a booster on 28th December 2021. Thereafter other individuals will sequentially become eligible to receive the booster dose once the period of 180 days has elapsed.

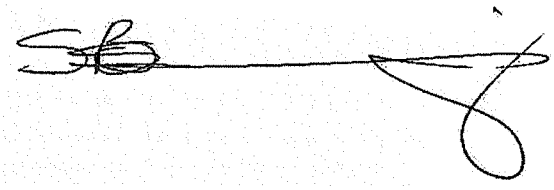
2.3. Immunocompromised individuals who have received an additional dose of the Cominarty® vaccine will become eligible to receive a booster dose 180 days after receiving the additional dose of the Cominarty® vaccine.

3. The following should be noted:

3.1 Only **homologous boosting** is currently permitted i.e. individuals may only receive the same vaccine that they received as their primary vaccination series.

3.2 All procedures regarding provision of primary doses remain unchanged during provision of booster doses.

3.3 **All booster doses must be correctly recorded on the EVDS.**



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