GOVERNMENT NOTICE DEPARTMENT OF CO-OPERATIVE GOVERNANCE

No. R. 2022

DISASTER MANAGEMENT ACT, 2002 AMENDMENTS TO REGULATIONS ISSUED IN TERMS OF SECTION 27(2)

I, Dr Nkosazana Dlamini Zuma, Minister of Cooperative Governance and Traditional Affairs, designated under section 3 of the Disaster Management Act, 2002 (Act No. 57 of 2002), having declared a national state of disaster, published in Government *Gazette* No. 43096 on 15 March 2020, and extended by Government Notices Nos. 646 of 5 June 2020, 765 of 13 July 2020, 889 of 15 August 2020, 995 of 14 September 2020, 1090 of 14 October 2020,1225 of 14 November 2020, 1341 of 11 December 2020, R. 15 of 13 January 2021, R. 86 of 11 February 2021, R. 193 of 11 March 2021, R. 333 of 14 April 2021, R. 424 of 14 May 2021, No. R. 476 of 30 May 2021, R. 493 of 11 June 2021, R. 611 of 12 July 2021 and R. 733 of 12 August 2021, No. R. 867 of 12 September 2021, No. R. 1031 of 13 October 2021, No. R. 1501 of 13 November 2021, No. R 1598 of 10 December 2021, No. R. 1672 of 14 January 2022, No. R1758 of 14 February 2022 and No. R. 1875 of 14 March 2022, after consultation with the relevant Cabinet members, hereby in terms of section 27(2) of the Disaster Management Act, 2002 make the Regulations in the Schedule.

DR NKOSAZANA DLAMINI ZUMA, MP MINISTER OF COOPERATIVE GOVERNANCE AND TRADITIONAL AFFAIRS DATE:

SCHEDULE

Definitions

1. In these Regulations, "the Regulations" means the regulations published by Government Notice No. R. 480 of 29 April 2020 as amended by Government Notices Nos. R. 608 of 28 May 2020, R. 714 of 25 June 2020, R.763 of 12 July 2020, R 846 of 31 July 2020 R. 891 of 17 August 2020, 999 of 18 September 2020, 1011 of 20 September 2020, 1053 of 1 October 2020, 1104 of 21 October 2020. 1199 of 11 November 2020, 1290 of 3 December 2020, 1346 of 15 December 2020, 1370 of 17 December 2020, 1421 of 24 December 2020, 1423 of 29 December 2020, 1435 of 29 December 2020, R. 11 of 11 January 2021, R. 69 of 1 February 2021, R. 92 of 13 February 2021, R. 93 of 13 February 2021, R. 152 of 28 February 2021, R. 284 of 30 March 2021, R. 376 of 22 April 2021, R. 477 of 30 May 2021, R. 530 of 15 June 2021, R. 532 of 17 June 2021, R. 565 of 27 June 2021, R. 567 of 29 June 2021, R. 610 of 11 July 2021, R. 612 of 14 July 2021, R. 614 of 14 July 2021 and R. 651 of 25 July 2021, No. R. 669 of 30 July 2021, No. R. 869 of 12 September 2021, No. R. 953 of 26 September 2021, No. R. 960 of 30 September 2021, No. R. 1024 of 11 October 2021, No. 1633 of 17 December 2021, No. R 1646 of 21 December 2021, No. R. 1659 of 30 December 2021, No. R. 1715 of 1 February 2022, No. R. 1759 of 15 February 2022, and No. R. 1915 of 22 March 2022.

Amendment of Classification of Regulations

2. The Classification of the Regulations is hereby amended by the deletion of Chapter 8 and the substitution with a new Chapter 8:

"CHAPTER 8

COVID-19 VACCINE INJURY NO-FAULT COMPENSATION SCHEME

- 88. Definitions
- 89. Establishment of COVID-19 Vaccine Injury No-Fault Compensation Scheme
- 90. Administration of the Scheme
- 91. Financial management and oversight of the Scheme
- 91A. Governance and Oversight
- 92. Adjudication Panel and Appeal Panel
- 93. Eligibility
- 94. Compensation
- 95. Submission of claims and procedure
- 96. Effect of submission of claims on right to claim damages in court proceedings
- 97. Causality determination
- 98. Adjudication of claims
- 99. Appeal
- 100. Duration and termination of Scheme
- 101. Contact details of Scheme".

Amendment of Chapter 8 to the Regulations

3. Chapter 8 of the Regulations is deleted and replaced with the following:

"CHAPTER 8 COVID-19 VACCINE INJURY NO-FAULT COMPENSATION SCHEME

Definitions

- **88.** For the purposes of this Chapter, unless the context otherwise indicates—**'claim'** means a claim made in terms of regulation 95;
- 'claimant' means a person who makes a claim in terms of regulation 95;
- **'COVID-19 Vaccine Injury'** means a serious injury as referred to in regulation 93(1) and specified as contemplated in regulation 93(3)(a), determined by NISEC to have been caused by a COVID-19 vaccine;
- 'NISEC' means the National Immunisation Safety Expert Committee, a non-statutory, standing, advisory committee of independent experts, appointed by the Cabinet member responsible for Health;
- **'Promotion of Administrative Justice Act, 2000'** means the Promotion of Administrative Justice Act, 2000 (Act No. 3 of 2000):
- 'Public Finance Management Act, 1999' means the Public Finance Management Act, 1999 (Act No. 1 of 1999); and

'the Scheme' means the COVID-19 Vaccine Injury No-Fault Compensation Scheme established by regulation 89.

Establishment of the COVID-19 Vaccine Injury No-Fault Compensation Scheme

- **89.** (1) A COVID-19 Vaccine Injury No-Fault Compensation Scheme is hereby established in terms of section 27(2)(*c*), (*m*) and (*n*) of the Act.
 - (2) The Scheme is an essential part of the COVID-19 vaccination roll-out, which is a critical component of the national plan and response to alleviate, contain and minimise the effects of the disaster, and ultimately to end the State of National Disaster.
 - (3) The purpose of the Scheme is to provide expeditious and easy access to compensation, for persons who suffer from a COVID-19 Vaccine Injury resulting from the administration of an approved COVID-19 vaccine, which was administered at an authorised facility within the Republic, without having to establish fault, as specified in directions issued by the Cabinet member responsible for Health in terms of regulation 93(3) and (4).
 - (4) In order to ensure the effective and efficient administration of the Scheme in a manner that ensures fairness in the assessment and administration of claims, and respects the constitutional rights of claimants, the Cabinet member responsible for Health must issue directions in terms of regulation 4 in consultation with the Cabinet member responsible for Finance in respect of—
 - (a) the requirements relating to the administration of the Scheme;
 - (b) the policy in respect of the administration of the Scheme;
 - (c) the reporting of a COVID-19 Vaccine Injury;
 - (d) the claims system;
 - (e) the eligibility requirements of the Scheme;
 - (e) the size of the Adjudication Panel, and the Appeal Panel;
 - (f) the qualifications for appointment of members of the Adjudication Panel, and members of the Appeal Panel; and
 - (g) any other matter relevant to the effective, efficient and fair administration of the Scheme.

Administration of the Scheme

- **90.** (1) The National Department of Health is responsible for the administration of the Scheme and its funds.
 - (2) The Director-General of the National Department of Health must establish administration of the scheme and its funding arrangements, in consultation with the National Treasury.

Financial management and oversight of the Scheme

- **91.** (1) The funds of the Scheme consist of—
 - (a) funds appropriated by an Act of Parliament to the vote of Health or from contingencies in terms of appropriation legislation or the Public Finance Management Act; and
 - (b) funds donated to the Scheme in accordance with existing donor procedures and requirements.
 - (2) The Cabinet member responsible for Finance may, in consultation with the Cabinet member responsible for Health, issue directions in terms of regulation 4 in respect of the requirements relating to the financial management and oversight of the Scheme that are in accordance with the Public Finance Management Act, 1999.

(3) The funds identified for the Scheme may not be utilised for purposes other than payment of compensation in terms of the Scheme, and the implementation and administration of the Scheme.

Governance and Oversight

91A. The Director General of Health, as the accounting officer, is responsible for overseeing the implementation of the Scheme in terms of this Chapter and the directions issued in terms hereof, and to provide advice to the Cabinet member responsible for Health and the Cabinet member responsible for Finance in respect of the implementation of the Scheme.

Establishment of the Adjudication Panel and Appeal Panel

- **92.** (1) The functionaries of the claims adjudication process of the Scheme hereby established are—
 - (a) The Adjudication Panel; and
 - (b) The Appeal Panel.
 - (2) (a) The Adjudication Panel shall comprise of at least 3, but no more than 5 members.
 - (b) The Cabinet member responsible for Health must appoint the members of the Adjudication Panel, following a nomination process, and subject to the criteria set out in directions and the call for nominations, relating to qualifications, expertise and experience.
 - (c) The members of the Adjudication panel must between them have medical expertise, financial expertise, and expertise in the adjudication of compensation of injuries.
 - (3) (a) The Appeal Panel shall comprise of 3 or more permanent members and 2 additional members, who may be appointed if additional expertise is required, who are appointed following a nomination process, and subject to the criteria set out in the directions and the call for nominations, relating to qualifications, expertise and experience.
 - (b) The Appeal Panel must be chaired by an advocate or attorney with at least 15 years' experience
 - (c) At least one of the permanent members of the Appeal Panel must have medical expertise and at least one of the permanent members of the Appeal Panel must have expertise in finance or in the assessment of damages.
 - (4) (a) The members of the Adjudication Panel and Appeal Panel must be independent from each other and possess appropriate expertise to fulfil their functions in respect of the implementation of the Scheme.
 - (b) The members of the Adjudication Panel and the permanent and additional members of the Appeal Panel are appointed for the period, and on the terms and conditions, determined in writing by the Cabinet member responsible for Health.
 - (c) The Director-General of the National Department of Health must provide necessary administrative support to the Adjudication Panel and Appeal Panel.
 - (5) The Adjudication Panel and Appeal Panel must take decisions and make assessments in accordance with—
 - (a) the requirements contained in regulation 93 and the directions issued in terms thereof; and
 - (b) the directions issued in terms of regulation 94.
 - (6) The Adjudication Panel and Appeal Panel must make decisions within the period specified in directions issued in terms of regulation 4 by the Cabinet member responsible for Health.
 - (7) The Adjudication Panel must further comply with regulation 98 in the adjudication of claims.

(8) The Appeal Panel must further comply with regulation 99 in the adjudication of claims.

Eligibility

- **93.** (1) A person who was vaccinated with a COVID-19 vaccine that was procured and distributed by the National Government and administered as part of the national vaccination programme as specified in directions as contemplated in subregulation (3)(c), and who suffers from or has suffered from a serious COVID-19 Vaccine Injury as specified in directions as contemplated in subregulation (3)(a), is eligible for compensation from the Scheme subject to the provisions of regulation 95 and the directions issued in terms of these regulations, and in particular directions contemplated in subregulation (3).
 - (2) A dependant of a deceased person, whose death was caused by a COVID-19 Vaccine Injury, is eligible for compensation from the Scheme.
 - (3) The Cabinet member responsible for Health, in consultation with the Cabinet member responsible for Finance, must issue directions in terms of regulation 4 specifying—
 - (a) the types of injury that constitute a CoVID 19 Vaccine injury that is covered by the Scheme;
 - (b) the types of loss or damage covered;
 - (c) the specific approved vaccines to be covered, which must be registered or otherwise approved by the South African Health Products Regulatory Authority and initially procured and distributed by the National Government;
 - (d) authorised sites in the Republic where COVID-19 vaccinations are officially administered:
 - (e) the timeline and duration of the COVID-19 Vaccine Injury after the administering of the vaccination that the Scheme will cover; and
 - (f) the period in respect of which claims for compensation may be submitted to the Scheme.

Compensation

- **94.** (1) The Cabinet member responsible for Health, in consultation with the Cabinet member responsible for Finance, must issue directions in terms of regulation 4 specifying the compensation that will be provided under the Scheme.
 - (2) Such compensation shall—
 - (a) be a capped amount to be outlined in the directions, in respect of the type of injury listed under a COVID-19 Vaccine Injury; and
 - (b) make provision for lumpsum compensation payments.
 - (3) The categories of compensation which may be awarded are for:
 - (a) death;
 - (b) permanent disability; and
 - (c) temporary disability.
 - (4) Compensation in terms of the Scheme shall only include those types of compensation specified in terms of directions.

Submission of claims and procedure

- **95.** (1) (a) Any person who maintains that he or she meets the requirements for claiming compensation from the Scheme in terms of regulation 93(1) or regulation 93(2) may submit a claim to the Scheme.
 - (b) A person who has submitted a claim for compensation under the Compensation for Occupational Injuries and Diseases Act, 130 of 1993 for an AEFI arising from vaccination is not eligible for compensation under the Scheme.
 - (2) The claim must be submitted—

- (a) by an eligible person or a person duly authorised to act on behalf of an eligible person to the Scheme simultaneously with, or after notification of an adverse event following immunisation to NISEC in respect of the COVID-19 vaccine; or
- (b) by the claimant to the Scheme.
- (3) Where a claimant submits a claim to the Scheme in terms of subregulation (2)(b) the Scheme must forward the claim and details of the alleged adverse event following immunisation to NISEC.
- (4) The Cabinet member responsible for Health must, after consultation with the Director General of the National Department of Health, issue directions in terms of regulation 4 specifying—
 - (a) procedures for instituting and submitting claims to the Scheme, including the form to be used for submitting claims;
 - (b) procedures for claims to be adjudicated by the adjudication panel, including the period in which a claim must be adjudicated; and
 - (c) procedures for appealing any decision of the adjudication panel or any determination of NISEC, including the periods in which a claim must be appealed and in which the appeal must be decided.

Effect of submission of claims on right to claim damages in court proceedings

- **96.** (1) Any person who elects to submit a claim to the Scheme in terms of these Regulations thereby agrees to follow and abide by the procedure for the adjudication and appeal of claims set out in regulations 98 and 99.
 - (2) The Cabinet member responsible for Health must ensure that the form for submitting a claim contemplated in regulation 95(4)(a) explains in plain language that a claimant who submits a claim agrees to follow and abide by the procedure set out in regulations 98 and 99

Causality determination

- **97.** (1) NISEC must determine the causality between the administration of a COVID-19 vaccine and the injury allegedly caused by the COVID-19 vaccine.
 - (2) To determine causality, NISEC must apply the World Health Organisation Methodology for Causality assessment of adverse events following immunisation, as may be published from time to time by the World Health Organisation.
 - (3) (a) In the event of NISEC finding causality, the Scheme must refer the claim to the Adjudication Panel for adjudication in terms of regulation 98.
 - (b) If NISEC finds no causality, the claimant may refer the matter to the Appeal Panel in terms of regulation 99(2).

Adjudication of claims

98. A claim contemplated in regulation 97(3)(a) will be adjudicated by the designated members of the Adjudication Panel, who must determine compensation in accordance with regulation 94 and directions issued by the Cabinet member responsible for Health.

Appeals

- 99. (1) A claimant who is dissatisfied by—
 - (a) a determination of non-causality by NISEC as contemplated by regulation 97(3)(b); or
 - (b) a decision of the adjudication panel as contemplated by regulation 98,

may appeal such decision to the Appeal Panel within the specified period.

- (2) The Appeal Panel hearing an appeal in terms of subregulation (1) may—
 - (a) confirm, vary or set aside the determination of NISEC or the decision of the Adjudication Panel whichever is applicable;
 - (b) if necessary, call for and receive new information or evidence relevant to the claim; and
 - (c) if necessary, appoint appropriately qualified persons (if already not part of the panel) to assist in the determination of the claim.
- (3) Any decision of the Appeal Panel is final and binding, save for where a claimant seeks to review the decision of the Appeal Panel.

Duration and termination of Scheme

- **100.** (1) This Chapter, the directions issued in terms hereof, and the existence of the Scheme—
 - (a) will not cease to operate or cease to be of force and effect merely because the State of National Disaster comes to an end; and
 - (b) will continue to operate and be of force and effect until a notice is published by the Cabinet member responsible for Health, in consultation with the Cabinet member responsible for Finance, in the Government Gazette terminating the Scheme.
 - (2) The Scheme shall not be terminated until-
 - (a) the period for the submissions of claims to the Scheme has expired; and
 - (b) all claims lodged with the Scheme have been finalised.
 - (3) Any funds which remain in the Scheme immediately before it is terminated shall be deposited into the National Revenue Fund, or shall otherwise be dealt with in terms of an Act of Parliament.

Contact details of Scheme

101. The contact details of the Scheme are as follows:

The Director General
National Department of Health
A B Xuma Building
128 Voortrekker Rd
Raslouw AH
PRETORIA
0157

eMail: <u>dg@health.gov.za</u> Tel (012) 395 8402

Commencement

4. These amendments to the Regulations shall be deemed to have come into operation on 22 April 2021.