NATIONAL DEPARTMENT OF HEALTH

INVITATION FOR PUBLIC COMMENT

COVID-19 VACCINE INJURY NO-FAULT COMPENSATION SCHEME

The Minister of Health hereby invites comments on:

(a) proposed amendments to the Regulations under the Disaster Management Act 57 of 2002 dealing with the Covid-19 Vaccine Injury No-Fault Compensation Scheme; and

(b) proposed Directions under the Disaster Management Act 57 of 2002 dealing with the Covid-19 Vaccine Injury No-Fault Compensation Scheme.

Any person may make written representations regarding these draft Amended Regulations and draft Directions, which are being published for comment on 31 March 2022.

The draft Amended Regulations and draft Directions are available on the following website:

www.health.gov.za

Representations must reach the National Department of Health **by 17h00 on Saturday 2 April 2022**.

Representations may be submitted by email to: AEFI@health.gov.za or electronically on the national Department of Health website at https://www.health.gov.za/public-comments-on-regulations/

GOVERNMENT NOTICE
DEPARTMENT OF HEALTH

No. 2022

DIRECTIONS ON THE ESTABLISHMENT OF A COVID-19 VACCINE INJURY NO-FAULT COMPENSATION SCHEME: ISSUED IN TERMS OF THE DISASTER MANAGEMENT ACT, 2002 (ACT NO.57 OF 2002)

I, Dr Matome Joseph Phaahla, Minister of Health, in consultation with the Minister of Finance, hereby publish Directions on the establishment of the COVID-19 Vaccine Injury No-Fault Compensation Scheme, in terms of Regulations 89(4), 93(3); 94(2) and 95(4) of the Regulations made in terms of section 27(2) of the Disaster Management Act, 2002 (Act No. 57 of 2002).

These Directions come into effect on the date of publication of this Notice in the Government Gazette.

DR MJ PHAAHLA (MP)
MINISTER OF HEALTH
DATE:

ARRANGEMENT OF DIRECTIONS

CHAPTER I

INTERPRETATION

1. Definitions

In these directions, a word or expression bears the meaning assigned to it in the Disaster Management Act or in the Regulations, and, unless the context indicates otherwise—

1.1 "**Adjudication Panel**" means the national panel established in terms of the regulations to determine eligibility and compensation for a COVID-19 vaccine injury;

1.2 "**AEFI**" means any untoward medical occurrence that may present after immunisation but which does not necessarily have a causal relationship with the usage of the vaccine;

1.3 "**Appeal Panel**" means the national panel established in terms of the regulations to determine the appeal of a claimant who is dissatisfied with a NISEC or Adjudication Panel outcome;

1.4 "**applicable vaccine**" means those COVID-19 vaccines listed in Schedule 1, as amended from time to time, which are procured and distributed by the National Government;

1.5 **"assessor"** means a person on a multi-disciplinary team responsible for investigation of AEFI in the private or public sector for the purpose of AEFI causality assessment by NISEC;

1.6 "**claimant**" means a person who makes a claim in terms of regulation 95;

1.7 "**claim form**" means the paper and digital application form in Schedule 4;

1.8 "**Compensation Table**" means the table provided in Schedule 6;

1.9 "**COVID-19 vaccine injury**" or "**vaccine injuries**" means a serious injury determined by NISEC to have been caused by a COVID-19 vaccine, and is limited to the injuries set out in paragraph 8;

1.10 "**Department**" means the National Department of Health;

1.11 "**Directions**" means these directions issued in terms of in terms of Regulations 89(4), 93(3); 94(2) and 95(4) of the Regulations made in terms of section 27(2) of the Disaster Management Act, 2002;

1.12 "**Director-General**" means the Director-General: Health;

1.13 "**dependant**" means the spouse or partner, or members of the person's immediate family in respect of whom the person is liable for family care and support;

1.14 "**eligible persons**" means a person who suffered a serious vaccine injury resulting from the administration of an applicable vaccine at an official vaccination site, or the dependent of a deceased person, who has suffered harm, loss or damage caused by the death of the deceased person, whose death was caused by a vaccine injury resulting from the administration of an applicable vaccine at an official vaccination site;

1.15 "**medical practitioner**" means a person registered as such under the Health Professions Act, 1974 (Act No. 56 of 1974);

1.16 "**Minister**" means the Cabinet member responsible for Health;

1.17 "**NISEC**" means the National Immunisation Safety Expert Committee, being a non-statutory, standing advisory committee of independent experts appointed by the Minister of Health;

1.18 "**PFMA**" means the Public Finance Management Act, 1999 (Act No.1 of 1999);

1.19 "**Regulations**" means the regulations published in terms of section 27(2) of the Disaster Managed Act, 2002 (Act No. 27 of 2002) under Government Notice No. R. 480 of 29 April 2020, as amended;

1.20 "**SAHPRA**" means the South African Health Products Regulatory Authority established under section 2 of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965);

1.21 "**Scheme**" means the COVID-19 Vaccine Injury No-Fault Compensation Scheme established by regulation 89(1) in terms of section 27(2)*(c)*, *(m)* and *(n)* of the Act;

1.22 **“Scheme Administrator”** means the person in the Department designated by the Director-General to administer the Scheme; and

1.23 "**vaccine card**" means the paper record of vaccinations administered to the vaccinee issued at the official vaccination site;

1.24 "**vaccine certificate**" means the digital record of vaccinations administered to the vaccinee and generated from the EVDS.

2. Background and principles

2.1 These Directions intend to facilitate the efficient administration and operation of the Scheme that has been established in the Regulations. The Scheme has been conceptualised in accordance with international best practice and is intended to provide compensation for vaccine injuries in a manner that is reliable, consistent and compassionate.

2.2 The Directions uphold and promote the core principles of the Scheme, as are set out in the Regulations.

CHAPTER II

ADMINISTRATION OF SCHEME

3. Administration

3.1 The Department is responsible for the administration of the Scheme and its funds and the Director-General shall be the accounting officer of the Scheme.

3.2 The Director-General shall perform the following functions:

3.2.1 provide the necessary human resources and technology to manage the Scheme;

3.2.2 approve and release payments to those awarded compensation by the adjudication panel or appeal panel, as the case may be; and

3.2.3 advise the Minister on any matter concerning compensation for persons who suffer from a vaccine injury.

3.3 The Director-General may, subject to such conditions as he or she may determine, delegate any of his or her powers or assign any of his or her duties, in writing, to an officer in the department, and may at any time cancel any such delegation or assignment.

3.4 A delegation or assignment under paragraph 3.3 –

3.4.1 shall not divest the Director-General of the power delegated or duty assigned, and he or she may at any time amend or set aside any decision made thereunder; and

3.4.2 shall not prevent the exercise of the power or the performance of the duty concerned by the Director-General himself or herself.

4. Financial management and oversight

4.1 The Scheme shall, subject to the provisions of the Regulations and these Directions, be under the control of the Director-General and its moneys shall be applied by the Director-General to:

4.1.1 the payment of compensation for vaccine injuries, as defined;

4.1.2 the payment of expenses incurred in or in connection with the performance of his functions in terms of paragraph 3.2;

4.1.3 the payment of any other expenditure reasonably incurred by the Director-General in the performance of his or her functions in terms of the Regulations.

4.2 The Director-General shall receive all funds appropriated to, received by or donated to the Scheme and shall be charged with the responsibility of accounting for all money received and utilised.

4.3 The Audit Committee of the Department must oversee the internal audit of the Scheme.

4.4 The Scheme will be audited by the Auditor-General of South Africa (AGSA), as part of the audit of the Department.

5. Functionaries of the Scheme

5.1 Regulation 92(1) establishes the following functionaries of the claims adjudication process of the Scheme:

5.1.1 the Adjudication Panel; and

5.1.2 the Appeal Panel.

5.2 The members of the Adjudication and Appeal Panels are appointed for the period, and on the terms and conditions, determined in writing by the Minister.

5.3 **The Adjudication Panel**

5.3.1 The Adjudication Panel will consist of, at least 3, and not more than 5 members appointed by the Minister following a nomination process, and subject to the criteria set out in these directions and the call for nominations, relating to qualifications, expertise and experience, and whose names shall be published on the Department's website.

5.3.2 The members of the Adjudication Panel must include:

5.3.2.1 at least one medical practitioner, registered with the Health Professions Council of South Africa, who is not part of the NISEC causality assessment, and who has experience in the assessment of compensation claims;

5.3.2.2 a person who has financial expertise; and

5.3.2.3 a person with experience in assessing personal damages and/or actuarial expertise, and who has experience in assessment of compensation claims.

5.4 The functions of the Adjudication Panel are to:

5.4.1 confirm eligibility of a claim;

5.4.2 confirm that the NISEC has concluded the investigation and determined that the injury was caused by an applicable vaccine;

5.4.3 confirm that the type of vaccine injury qualifies for compensation;

5.4.4 confirm that the vaccination was administered as a part of the official vaccination programme at a facility authorised by the department of health to vaccinate;

5.4.5 establish the severity and duration of the injury; and

5.4.6 determine the compensation payable, in line with Schedule 6.

5.5 The Adjudication Panel may obtain expert opinions and advice where it deems it is necessary for the proper adjudication of a claim, and may refer a claimant for an external expert assessment.

5.6 **The Appeal Panel**

5.6.1 The Appeal Panel will consist 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 these directions and the call for nominations, relating to qualifications, expertise and experience, and whose names shall be published on the Department of Health's website.

5.6.2 The 3 permanent members of the Appeal Panel must include at least:

5.6.2.1 an advocate or attorney with at least 15 years' experience, who is the Chairperson of the Panel;

5.6.2.2 a medical practitioner or specialist, registered with the Health Professions Council of South Africa, who is not part of the NISEC causality assessment or the adjudication panel, and who has experience in assessment of compensation claims;

5.6.2.3 a person who has financial expertise; and

5.6.2.4 a person with experience in assessing personal damages and/or actuarial expertise, who has experience in assessment of compensation claims and is not linked to the adjudication panel.

5.6.3 The Minister may appoint 2 (two) additional non-permanent members to the Appeal Panel if, in the opinion of the chairperson of the appeal panel:

5.6.3.1 the issues before the Appeal Panel require an individual or individuals with particular expertise and/or skills; or

5.6.3.2 the appointment of further members is required for the Appeal Panel to operate effectively.

5.6.4 The Appeal Panel may obtain expert opinions and advice where it deems it is necessary for the proper adjudication of a claim, and may refer a claimant for an external expert assessment.

CHAPTER III

COMPENSATION FOR VACCINE INJURY

6. Eligibility

In terms of regulations 93(1) and 93(2), any person who has suffered a serious COVID-19 injury as specified in paragraph 8 caused by the administration of an applicable vaccine referred to in paragraph 7 and Schedule 1, or the dependent of a deceased person whose death resulted from the administration of an applicable vaccine, at an official vaccination site referred to in paragraph 9 and Schedule 2, may be eligible for compensation from the Scheme.

7. Applicable vaccines

Applicable vaccines are those set out in Schedule 1.

8. Types of vaccine injuries compensated

8.1 Vaccine injuries that are covered by the Scheme are serious injuries resulting in:

8.1.1 permanent physical or mental impairment;

8.1.2 temporary physical or mental impairment;

8.1.3 death.

9. Official vaccination sites

Those public and privately managed sites within the Republic that have been designated by the Department for the administration of applicable vaccines and which are authorised and listed in the Master Facilities List (MFL) of the Department.

10. **Duration of injury and period of applicable vaccinations**

10.1 The duration of the injury that may qualify for compensation may be determined as temporary (completely resolves after any length of time) or permanent (injury does not resolve).

10.2 The period of applicable vaccinations commences from 17th May 2021 and ends one year after the last dose of applicable vaccine is administered.

11. **Period in respect of which claims may be instituted**

11.1 A claim for compensation for an AEFI that results in causally linked injury must be lodged with the Administrator within 30 days after the claimant, or duly authorised person have been informed, in writing, of the outcome of a NISEC causality assessment by the Administrator.

11.2 Once the Administrator informs the claimant, or duly authorised person, that NISEC has determined that the injury was caused by an applicable vaccine, the claimant may lodge the claim.

CHAPTER IV

CLAIMS FOR COMPENSATION

12. **Procedure for reporting an alleged adverse event**

12.1 All claims for compensation in respect of a vaccine injury must commence with reporting of the AEFI, followed by investigation of the AEFI, and causality assessment, using the reporting options set out in Schedule 3.

12.2 An AEFI must be reported within 30 days of the onset of the AEFI, through the mechanism specified in Schedule 3.

12.3 **Powers of the Department regarding AEFI investigations**

12.3.1 NISEC is responsible for determination of causality of the alleged vaccine injury.

12.3.2 The Department assessor/s seized with collection of the evidence required by NISEC in the determination of causality may investigate any matter that they may deem necessary for the performance of their functions.

12.3.3 In the course of any such investigation, an assessor may –

12.3.3.1 without previous notice, at all reasonable times enter any premises, and take an interpreter or other assistant with them onto the premises;

12.3.3.2 whilst on the premises, or at any time thereafter, question any person who is or was on the premises, either alone or in the presence of any other person on any matter to which the Regulations or these Directions relate;

12.3.3.3 order any person who has control over or custody of any book, document, or thing on or in those premises to produce forthwith, or at such time and place as may be determine by the assessor, such book, document or thing;

12.3.3.4 seize any book, document or thing which in the assessor/s opinion may serve as evidence in any matter in terms of the Regulations or these Directions; and

12.3.3.5 examine or cause to be examined any book, document or thing produced or seized in terms of paragraph 12.3.3.3 or 12.3.3.4, and make extracts therefrom or copies thereof, and order any person who is in the assessors' opinion qualified to explain any entry therein.

13. Causality assessment

13.1 Determination of causality

13.1.1 Pursuant to the report of an AEFI in terms of **Error! Reference source not found.**, NISEC must make a recommendation as to whether the claimant's reported vaccine injury meets the requirements of being causally linked to the applicable vaccine.

14. Procedure for lodging a claim

14.1 When NISEC determines that an applicable vaccine has been causally linked to an injury, NISEC must inform the Department, and the Department must then notify the Scheme Administrator within 28 days of the NISEC determination.

14.2 The Scheme Administrator must inform the eligible person, or the dependant, or the parent or legal guardian in the case of a child of the causality determination and assist with the lodging of a compensation claim.

14.3 Claims must be lodged by—

14.3.1 an eligible person; or

14.3.2 where the eligible person lacks full capacity, a person duly authorised to act on behalf of the eligible person.

14.4 When the claimant referred to in paragraph **Error! Reference source not found.** is a dependant, such a claim must be indicated in section A of the Claim Form in Annexure 3, and must include—

14.4.1 the death certificate of the deceased person;

14.4.2 in the case of a claim made by a spouse, a certified copy of the marriage certificate;

14.4.3 in the case of a claim made by a child, a certified copy of the claimant's unabridged birth certificate;

14.4.4 in the case of a claim made by other dependants, documentary evidence that the deceased person was liable for family care and support.

14.5 Following the submission of a claim in accordance with the procedure set out in this paragraph—

14.5.1 the claimant will be notified and provided with the date on which their AEFI was received by NISEC;

14.5.2 the AEFI will be investigated by the relevant assessor as identified by the Department in the specified province, and once the investigation is concluded;

14.5.3 NISEC shall consider the AEFI and assess whether the injury was caused by the applicable vaccine;

14.5.4 to determine causality, NISEC shall apply the World Health Organisation Methodology for Causality assessment of AEFI as may be published from

time to time by the World Health Organisation;

14.5.5 the assessment referred to in 13.1.1 shall be based on a balance of probabilities.

15. Quantum assessment

15.1 Assessment process

15.1.1 Upon receipt of a claim that is determined by NISEC to be causally linked to an applicable vaccine, the designated members of the Adjudication Panel must determine the eligibility of the claim in terms of regulation 93 and consider and assess the quantum of that particular claim.

15.1.2 The assessment referred to in 15.1.1 must be made within 30 days from the date of receipt of the claim from the eligible person, or the dependant, or the parent or legal guardian in the case of a child.

15.1.3 The Adjudication Panel, at its discretion, may—

15.1.3.1 request a member who is a medical practitioner to examine the patient;

15.1.3.2 accept the referring or accompanying physician's report regarding the assessment of disability;

15.1.3.3 refer the claimant for an expert assessment**.**

15.2 Recommendation on quantum and structure of compensation

15.2.1 The Minister must determine a table to be used for the quantification of the percentage of disability for the purposes of determining compensation.

15.2.2 Pursuant to the assessment of a claim in terms of 15.1, the Adjudication Panel must make a recommendation on the quantum and structure of compensation for the claim to the Director General for approval in accordance with the principles set out in Chapter V.

15.2.3 The Director General will authorise the Department to make the approved payments.

16. Appeals

16.1 Appeal by a claimant

16.1.1 Any claimant who is dissatisfied by:

16.1.1.1 the determination by NISEC that the reported AEFI is not causally linked to an applicable vaccine; or

16.1.1.2 a determination by the Adjudication Panel that the claim is ineligible in terms of regulation 93, or

16.1.1.3 the quantum and structure of compensation determined by the Adjudication Panel,

may appeal against that decision to the Appeal Panel.

16.1.2 The operation of any decision that is the subject of an appeal under 16.1.1 shall be suspended pending the decision of the Appeal Panel on such appeal.

16.1.3 An appeal contemplated in 16.1.1 shall be lodged in writing on the prescribed Appeal Form in Schedule 4. Such an appeal shall be lodged within 90 days from the date on which the claimant is notified of the outcome of his or her claim by the Adjudication Panel.

16.1.4 Condonation for the late filing of an appeal may be permitted by the chairperson of the Appeal Panel on good cause shown.

16.1.5 A claimant who lodges an appeal may be permitted to appear, either by themselves or with a medical practitioner if the rejection was on the grounds of non-causality, or another representative if the objection relates to the awarded quantum and structure of a compensation award, in person before the Appeal Panel.

16.1.6 The Appeal Panel may, at any stage before it reaches a decision on appeal, call for new information or further evidence relevant to the claim, including by:

16.1.6.1 in writing requesting any person, in its opinion, who may be able to give material information concerning the subject of the appeal or who, in its

opinion, has in their position or custody or under their control any document which has any bearing upon the subject of the appeal, to produce such an opinion or document, or the copy of such a document; and

16.1.6.2 that may be retained by the Appeal Panel for examination.

16.1.7 The Appeal Panel must, within 60 days of receipt of either the Appeal Form contemplated in subsection 16.1.3 or the receipt of all the information contemplated in 16.1.6, whichever is the latter, either:

16.1.7.1 confirm the decision of the Adjudication Panel;

16.1.7.2 set aside the decision of the Adjudication Panel; or

16.1.7.3 amend the decision of the Adjudication Panel, alternatively, substitute the decision of the Adjudication Panel with a decision of its own.

16.1.8 The decision of the Appeal Panel (a consensus of the members of the Appeal Panel sitting in respect of a particular appeal) shall be in writing and a copy of such decision shall be provided to the claimant as soon as possible after such decision is taken. A copy of the decision must also be communicated to the Director-General.

17. **Disclosure of information**

17.1 No person shall disclose any information obtained by himself or herself in the performance of their functions in terms of the provisions of the Regulations or these Directions, except –

17.1.1 to the extent to which it may be necessary for the proper administration of a provision of the Regulations or these Directions; or

17.1.2 for the purposes of the administration of justice; or

17.1.3 at the request of the Minister or any other person entitled thereto.

17.2 A medical or other registered health practitioner may disclose information that is necessary for the proper administration of a provision of the Regulations or these Directions, notwithstanding any other law that may otherwise prohibit such disclosure.

CHAPTER V

COMPENSATION

18. Quantum and Structure of Compensation

18.1 The quantum of compensation will be determined by the Adjudication in accordance with the Compensation Table provided in Schedule 6 and approved by the Director General.

18.2 Compensation shall be a capped amount in respect of the type of injury listed under a COVID-19 Vaccine Injury and shall make provision for lump sum compensation payments.

18.3 Compensation in terms of the Scheme only covers those aspects specified in Schedule 6.

18.4 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 shall not be eligible for compensation under the Regulations and these Directions.

SCHEDULE 1

APPLICABLE VACCINES

The following vaccines approved for use by the South African Health Products Regulatory Authority (SAHPRA):

1. Comirnaty and Pfizer-BioNTech COVID-19 Vaccine

2. Johnson & Johnson's Janssen COVID-19 Vaccine, Name: JNJ-78436735, Manufacturer: Janssen Pharmaceuticals Companies of Johnson & Johnson,

that were donated to the National Department of Health, obtained by the Government of South Africa in terms of the CoVAX facility, or which were procured by the Government of the Republic of South Africa acting through the National Department of Health in terms of the following agreements:

1. with Pfizer Laboratories Proprietary Limited dated 26 March 2021 and 04 April 2021;

2. with Janssen Pharmaceutica NV dated dated 16 February and18 April 2021.

SCHEDULE 2

OFFICIAL VACCINATION FACILITIES

As registered on the Master Facilities List (MFL) and published on the Department website from time to time.

SCHEDULE 3

AEFI REPORTING OPTIONS

1. The reporting of an Adverse Event Following Immunisation (AEFI) is **not a claim for compensation** but is a prerequisite for an investigation into causality which may result in a claim.

2. Adverse Events Following Immunisation (AEFI) may be reported in any one of the following ways:
   - MedSafety Mobile application of SAHPRA
   - At the health facility – paper-based forms or app CASE REPORT FORM (CRF) FOR ADVERSE EVENTS FOLLOWING IMMUNISATION (AEFI)
   - On the COVID-19 hot line 0800 029 999

   all of which methods are reported through aefi@health.gov.za to the Vigilance Hub, which is managed by SAHPRA and visible to the National Department of Health, as a common data base of AEFI.

3. The reports are classified as:
   - Minor – no further investigation
   - Severe trigger event
     - minor outcome – no further investigation
     - serious outcome
       - admission
       - disability (temporary or permanent)
       - death
       - congenital birth defect

4. A reported AEFI [Adverse Events Following Immunization Case Report Form (AEFI CRF)] is submitted to the health establishment whose investigators use a Case Investigation Form (CIF) to collect details related to the vaccination and the event.

5. The results from the investigation are submitted to the NDOH and become part of the running 'line list' for the province.

6. The completed CIF, accompanied by the full dossier of patient information, is submitted to NISEC where the (online) 'Worksheet for AEFI Causality Assessment' is followed to determine causality. Those cases where the injury is **"Consistent with causal association to immunisation" must be reported to the Scheme Administrator in the Department** for the eligible person to be informed who may submit a claim for

compensation at the same time as the feedback is provided on outcome to the provincial DOH for clinical follow-up.

Compensation Claim

7. A duplicate of the full package from NISEC must be submitted to the Scheme Administrator within 28 days of the conclusion of the NISEC assessment.

8. The Administrator must contact the claimant to:
   8.1 advise the person that they may lodge a claim;
   8.2 if the person chooses to lodge a claim, obtain consent for sharing the package of clinical investigation results with the Adjudication Panel,
   8.3 support the claimant, should he or she wish to formally lodge a claim for compensation, and
   8.4 collect administrative information for identification of the claimant.

9. The Administrator must:
   9.1 arrange for meetings of the Adjudication Panel and prepare the documents related to claims lodged since the previous meeting,
   9.2 keep a record of the proceedings and outcome of each adjudication and award,
   9.3 prepare the request for payment for the Director General to Authorise,
   9.4 ensure that payment is made, and
   9.5 provide feedback to the claimant.

SCHEDULE 4

CLAIM FORM

This form may be updated from time to time to meet the needs of information requirements to properly process and assess claims as they might be identified, and any updated versions of the form will be available on the National Department of Health website, https://www.health.gov.za/covid19/ .

EPID	S O A -	-	-	-
Or SAHPRA	Country	Province	District	Year
	Case no			

Date received	*Stage*	*Signature*
	NISEC	
	NDOH Administrator	
	Claim (Claimant)	

For Office use only:

Date vaccine injured party notified, by Administrator regarding NISEC causality assessment outcome: D D / M M / Y Y Y Y

NISEC causality outcome and case dossier attached ☐ **YES** ☐ **NO**

All fields in this form are mandatory, unless indicated 'if applicable'.
Provide the requested information or tick the appropriate box.

SECTION A: IDENTIFYING INFORMATION

Date of Claim submitted: D D / M M / Y Y Y Y

Claimant name & surname:

_____

Vaccine injured person name & surname:

_____

Relationship to the vaccine injured party: Eligible person / Dependent / Authorized person / Parent or legal guardian in the case of a child or Other please specify

_____

Where a dependant is the claimant, please attach:

- Vaccine injured party death certificate: ☐ YES ☐ NO
- For a spouse the marriage certificate: ☐ YES ☐ NO
- For Child dependent, a unabridged birth certificate: ☐ YES ☐ NO
- Other dependants to submit proof as required

Claimant residential address*:*

_____

_____

_____

Mobile no: _____**Telephone no:**

_____

Email:

_____

Sex: ☐ M ☐ F ☐ Other

Form of Identification attached of Claimant: ID / Passport / Other – Please specify:

_____

ID number: ☐☐☐☐☐☐☐☐☐☐☐☐☐

Claimant banking details:

Account holder name:_____

_____

_____

Bank:_____

_____

Branch:_____

_____

Account type:_____

Account number:_____

Bank stamp:

Validate banking details at your bank, alternatively submit stamped bank statement not older than 3 months confirming these details.

Passport number: _____ **Date of birth**: D D / M M / Y Y Y Y	

SECTION B: VACCINE INFORMATION (Please attach a copy of the Vaccine certificate OR Vaccination Card)

Health facility / vaccination center name: _____ ☐ **DoH** ☐ **Private** ☐ **NGO**

Address / location:

_____

Vaccine administered

Vaccine/s given (Use trade name)	Date vaccinated	Time vaccinated	Dose number (1st, 2nd)	Batch/ Lot number

Vaccination code received from EVDS	

SECTION C: DESCRIBE THE ADVERSE EVENT REPORTED / TYPE OF VACCINE INJURY

Date & time AEFI started: D D / M M / Y Y Y Y ☐☐ Hr ☐☐ Min

Describe vaccine recipient's or caregiver's concern (AEFI signs and symptoms). Use additional sheet if needed

Final Diagnoses:

_____

_____

_____

_____

_____

_____

AEFI reported through: Health System/Facility ☐ **MedSafety application** ☐ **COVID-19 Call Centre** ☐

Not reported, please provide details:

_____

_____

_____

SECTION D: TYPE OF VACCINE INJURY

Is this event a serious AEFI? ☐ Yes ☐ No

- ☐ Death ☐ Disability

Describe injury:

_____

SECTION E: THE OUTCOME OF THE ADVERSE EVENT REPORTED

☐ Recovering ☐ Recovered fully (no complications) ☐ Not Recovered ☐ Unknown

☐ Recovered with complications; Specify:

_____

_____

_____

Treating Clinician name: _____**Practice number:**

_____

Telephone number: _____ **Clinician address:** _____ _____ ☐ Died ➔ Date of death: D D / M M / Y Y Y Y ➔ Autopsy: ☐ Yes ☐ No ☐ Unknown ☐ Hospitalisation ➔ Date of admission: D D / M M / Y Y Y Y ➔ Name of hospital: _____ Hospital number: _____
Claimant Signature: **Date:** : D D / M M / Y Y Y Y

FOR OFFICE USE ONLY - SECTION F: CLAIM MOVEMENT AND PROCESSING	
Adjudication panel evaluated claim: ☐ Yes ☐ No Date claim evaluated: D D / M M / Y Y Y Y	Adjudication outcome received: ☐ Yes ☐ No Date the outcome received by Administrator: D D / M M / Y Y Y Y Date claimant informed of adjudication panel outcome: D D / M M / Y Y Y Y

CONSENT CLAUSE FOR COLLECTION AND PROCESSING OF PERSONAL INFORMATION

By their signature below, the claimant or vaccine recipient or relative (in the event of the vaccine recipient being unresponsive or has demised) or caregiver (in the case of a child) hereby provides consent to the collection and processing of their personal information (as set out in this No Fault Compensation Claim Form) by the National Department of Health and third parties appointed by it (the "Department") for the purposes of No Fault Compensation Claim Administration. The claim process will investigate and asses potential adverse events related to the use of COVID-19 vaccines The claimant, vaccine recipient or relative (in the event of the vaccine recipient being unresponsive or has demised) or caregiver (in the case of a child) acknowledges that this information may be used i) to access all medical and clinical records for the purpose of claim processing or case investigation, when required; ii) in the generation of statistics; and iii) to make policy decisions relating to vaccine safety and efficacy. This consent may be withdrawn at any time, and the claimant, vaccine recipient or relative (in the event of the vaccine recipient being unresponsive or has demised) or caregiver (in the case of a child) may, at any time, object to the collection and processing of their personal information, by contacting the National Department of Health.

The Department undertakes to process the personal information contained in this No Fault Compensation Claim form, and collected during the process of claim processing and case investigation in a manner that adheres to the Protection of Personal Information Act. The information will not be stored (in a manner that identifies the vaccine recipient) for any longer than is necessary to achieve the purpose for which the information was collected, unless the Department has a lawful basis to do so. If the vaccine recipient or relative (in the event of the vaccine recipient being unresponsive or has demised) or caregiver (in the case of a child)

wishes to access and/or rectify their personal information, they may do so by contacting the National Department of Health.

Claimant: _____ (Name and Surname)

Signed by the claimant/ vaccine recipient / relative / caregiver*

_____	_____	_____
Name and Surname	**Signature**	**Date**

*Delete what is not applicable

SCHEDULE 5

APPEAL FORM

This form may be updated from time to time to meet the needs of information requirements to properly process and assess appeals as they might be identified, and any updated versions of the form will be available on the National Department of Health website, https://www.health.gov.za/covid19/ .

EPID | S | O | A | - | | | | - | | | | - | | | | - | | | |

Or SAHPRA **Country - Province - District - Year - Case no**

Date received	*Stage*	*Signature*
	NISEC	
	NDOH Administrator	
	Claim (Claimant)	

For Office use only:

Date vaccine injured party notified, by Administrator regarding NISEC causality assessment outcome: D D / M M / Y Y Y Y

NISEC causality outcome and case dossier attached ☐ **YES** ☐ **NO**

All fields in this form are mandatory, unless indicated 'if applicable'.
Provide the requested information or tick the appropriate box.

SECTION A: IDENTIFYING INFORMATION

Date of Claim submitted: D D / M M / Y Y Y Y

Claimant name & surname:

_____

Vaccine injured person name & surname:

_____

Relationship to the vaccine injured party: Eligible person / Dependent / Authorized person / Parent or legal guardian in the case of a child or Other please specify

_____

Where a dependant is the claimant, please attach:

- Vaccine injured party death certificate: ☐ YES ☐ NO
- For a spouse the marriage certificate: ☐ YES ☐ NO
- For Child dependent, a unabridged birth certificate: ☐ YES ☐ NO
- Other dependants to submit proof as required

Claimant residential address:

_____

_____

Mobile no: _____**Telephone no:**

_____

Email:

_____

Sex: ☐ M ☐ F ☐ Other

Form of Identification attached of Claimant: ID / Passport / Other – Please specify:

_____

ID number: ☐☐☐☐☐☐☐☐☐☐☐☐☐

Claimant banking details:

Account holder name:_____

_____

Bank:_____

Branch:_____

Account type:_____

Account number:_____

Bank stamp:

Validate banking details at your bank, alternatively submit stamped bank statement not older than 3 months confirming these details.

Passport number: _____ **Date of birth**: D D / M M / Y Y Y Y	

SECTION B: ADJUDICATION OUTCOME

Date of Adjudication panel evaluation: D D / M M / Y Y Y Y

Adjudication outcome report attached: ☐ **YES** ☐ **NO**

Adjudication Summary Outcome:

Compensation offered	☐ **YES** ☐ **NO**	**Amount Offered: R**

SECTION C: APPEAL REQUEST

Date compensation offered rejected: D D / M M / Y Y Y Y **Written notice of rejection provided:** ☐ **YES** ☐ **NO**

Compensation Paid: ☐ **YES** ☐ **NO** **If Yes, please note date compensation received by claimant:** D D / M M / Y Y Y Y

Please provide reasons for appeal:

_____
_____
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_____

Claimant Signature: **Date:** D D / M M / Y Y Y Y

SECTION D: APPEAL PROCESS

Date appeal request received by Administrator: D D / M M / Y Y Y Y

Date appeal request submitted to Appeal Panel: D D / M M / Y Y Y Y

FOR OFFICE USE ONLY - SECTION F: CLAIM MOVEMENT AND PROCESSING

Appeal panel evaluated request: ☐ Yes ☐ No Date claim evaluated: D D / M M / Y Y Y Y	Appeal outcome received: ☐ Yes ☐ No Date the outcome received by Administrator: D D / M M / Y Y Y Y Date claimant informed of appeal panel outcome: D D / M M / Y Y Y Y

SCHEDULE 6

COMPENSATION TABLE

In the event that a Payment is approved either by the Adjudication Panel or the Appeals Panel then, the sum to be paid shall be calculated using a Quantum Assessment using the following methodology:

a. Death Benefit

An amount of R150,000 in the event of a death.

b. Permanent Disability Benefit

The proportions for permanent disability are calculated as a ratio of the amount payable in the event of death, which is R150 000.

The harm factors resulting from the Vaccine or its administration are:

a.	1.0	if death (included as a reference point for determination)
b.	1.5	if the Impairment is equal to or greater than 75%
c.	1.0	if the Impairment is equal to or greater than 50% but below 75%
d.	0.5	if the Impairment is equal to or greater than 25% but below 50%
e.	0.25	if the Impairment is equal to or greater than 10% but below 25%
f.	0.10	if the Impairment is below equal to or greater than 5% but below 10%
g.	0	No compensation will be paid if the impairment is below 5%

c. Temporary Disability Benefit

For a person with a serious vaccine injury (in excess of 25% impairment) in line with the approved list of vaccine injuries in Schedule 2, a fixed temporary compensation amount of R5,000 per month of disability, up to a maximum of 6 months, will be paid, provided that the duration of the temporary disability is at least one month and provided that the claimant does not receive a benefit for the same injury under COIDA.

A person may claim for both temporary and permanent disability, where applicable.

Temporary disability payments may be made prior to the finalisation of a claim for permanent disability.