

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/>

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

1.11 **"Directions**

- 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

- 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.

- 5.6.4 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 ap TJET54pETQq0.0

- 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

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 - - - -

Number:

Or SAHPRA

reference number:

For Office use only:

Date vaccine injured party notified, by Administrator regarding NISEC causality assessment outcome: DD / MM / YYYY

NISEC causality outcome and case dossier attached YES NO

Passport number: _____

Date of birth: DD/MM/YYYY

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 (1 st , 2 nd)	Batch/ Lot number

Vaccination code received from EVDS _____

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

Date & time AEFI started: DD/MM/YYYY 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 DTf115 5 83ab(h iA)-l(ys)iA

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

Passport number: _____		
Date of birth: <u>DD/MM/YYYY</u>		
SECTION B: ADJUDICATION OUTCOME		
Date of Adjudication panel evaluation: <u>DD/MM/YYYY</u>		
Adjudication outcome report attached: <input type="checkbox"/> YES <input type="checkbox"/> NO		
Adjudication Summary Outcome:		
Compensation offered	<input type="checkbox"/> YES <input type="checkbox"/> NO	Amount Offered: R
SECTION C: APPEAL REQUEST		
Date compensation offered rejected: <u>DD/MM/YYYY</u> Written notice of rejection provided: <input type="checkbox"/> YES <input type="checkbox"/> NO		
Compensation Paid: <input type="checkbox"/> YES <input type="checkbox"/>		

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.

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