Western Cape Government

Department of Health
Chief Directorate: Emergency and Clinical Services Support

Directorate: Service Priorities Coordination
Enquiries: Dr H Goeiman & Ms C Lawrence

TO: **DDG: Chief of Operations**
Chief Directors: MHS, RHS, STRATEGY
Directors: EMS, FPS, SPC, HIA, Clinical Service Improvement, Medicine Management, Substructures, Districts
Head of Institutions
Director: City Health
Managers: Private Hospitals, Private Clinics, Pharmacies
Managers: Departments – Social Development, Basic Education & Correctional Services

CIRCULAR H 05 **/ 2022**

VACCINE SAFETY SURVEILLANCE: UPDATE ON REQUIRED DOCUMENTATION FOR AEFI CASE REPORTING AND INVESTIGATION (TO BE READ IN CONJUNCTION WITH CIRCULAR H72/2021).

Please find attached National Vaccination Programme Circular 1 of 2022.

Obligations in terms of the Protection of Personal Information Act (POPIA), effective 1 July 2021 has necessitated the development of a Consent Form to accompany the Case Report Form (CRF) for the reporting and investigation of adverse events and the subsequent sharing of personal information. These include Adverse Events Following Immunisation (AEFI) and Adverse Events of Special Interests (AESI) cases.

Going forward, please obtain consent from the vaccinee, caregiver or family member and submit the document with the case reporting form (CRF).

Please note there have been no changes to the CRF itself, only the addition of the Consent Form (see attached).

Kindly note any further updates or additions from National Department of Health with regards to AEFI and vaccine safety surveillance will be communicated in due course.

Please direct queries to Dr Hilary Goeiman (Hilary.Goeiman@westerncape.gov.za) or Ms Charlene Lawrence (Charlene.Lawrence@westerncape.gov.za)

Digitally signed by Juanita O. Arendse
Date: 2022.01.26 20:15:27 +02'00'

JO ARENDSE
CHIEF DIRECTOR: ECSS
DATE: 26 January 2022

DIRECTOR GENERAL
HEALTH
REPUBLIC OF SOUTH AFRICA

PRETORIA
Private Bag X828, PRETORIA, 0001, Dr AB Xuma Building, 1112 Voortrekker Rd, Pretoria 351-JR, Pretoria, 0187, Tel (012) 395 8402
CAPE TOWN
P.O. Box 3875, CAPE TOWN, 8000, 103 Parliament Towers, Room 615, 120 Plain Street, CAPE TOWN, 8000 Tel (021) 461 2040 Fax (021) 461 6864

TO:
HEADS OF PROVINCIAL HEALTH DEPARTMENTS
HEADS OF PHARMACEUTICAL SERVICES
DISTRICT MANAGERS
HOSPITAL CEOs and CLINICAL MANAGERS
EPI MANAGERS
AEFI COORDINATORS
HEALTHCARE MANAGERS AND PROFESSIONALS

NATIONAL VACCINATION PROGRAMME CIRCULAR 1 OF 2022

ADVERSE EVENT FOLLOWING IMMUNISATION (AEFI) REPORTING AND INVESTIGATION

1. Immunisation is among the most successful and cost-effective public health interventions. It is common that the benefits of immunisation are often not visible, particularly if the target disease incidence is low. In contrast, adverse effects that follow immunisation are promptly noticeable, especially when the vaccinee was apparently healthy at the time of immunisation.

2. Regulation 40 (3) of the General regulation made in terms of the Medicine and Related Substances Act 101 of 1965 indicates that "A health care provider, veterinarian or any other person should inform the Authority, in the manner as determined by the Authority, of any-(a) suspected adverse drug reactions; or (b) new or existing safety, quality or effectiveness concerns, occurring as a result of the use of any medicine or scheduled substance."

3. Surveillance of adverse events following immunisation (AEFI) is essential to safeguard public confidence in vaccines used in the South African vaccination programme. The National Immunisation Expert Committee (NISEC) advises and monitors vaccine safety related events though causality assessment. Causality assessment requires AEFI to be investigated fully at a district/provincial level. This include completion of all relevant case reporting forms (CRF), case investigation forms (CIF), and collation of the clinical records, laboratory results and medical history of the vaccinee.

4. All health care providers or any other person who identify, treat or report an AEFI, are requested to share all requested information to facilitate AEFI reporting and

investigation as required by the relevant regulations with the district/provincial AEFI coordinators in a timely manner.

5. To address concerns regarding sharing of the vaccinee's personal information, the CRF (attached) and the MedSafety application terms has been updated to include a section whereby the vaccinee (or family member) provides informed consent for the necessary information to be provided to the relevant authority. Where an AEFI has been reported on a CRF that does not include the informed consent section, the additional consent form can be completed by the vaccinee/caregiver or family member.

DR SSS BUTHELEZI
DIRECTOR-GENERAL: HEALTH
DATE: 10.01.2022

health
Department:
Health
REPUBLIC OF SOUTH AFRICA

Private Bag X828, PRETORIA, 0001 Dr AB Xuma Building1112 Voortrekker Road, Pretoria Townlands 351-JR, PRETORIA, 0187 Tel (012) 395 8000, Fax (012) 395 8918

CONSENT CLAUSE FOR COLLECTION AND PROCESSING OF PERSONAL INFORMATION

By their signature below, 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) hereby provides consent to the collection and processing of their personal information (as set out in this Case Reporting Form) by the National Department of Health and third parties appointed by it (the "Department") for the purposes of investigating and assessing potential adverse events related to a vaccine/s received.

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) acknowledges that this information may be used i) to access all medical and clinical records for the purpose of 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 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 Department (AEFI@heath.gov.za) and the South African Health Products Regulatory Authority (adr@sahpra.org.za).

The Department undertakes to process the personal information contained in this Case Reporting Form, and collected during the process of 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 Department (AEFI@heath.gov.za).

Vaccine recipient: _____ (Name and Surname)
Signed by the vaccine recipient / relative / caregiver*

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

**Delete what is not applicable*

health
Department: Health
REPUBLIC OF SOUTH AFRICA

COVID-19

CASE REPORTING FORM (CRF) FOR SUSPECTED ADVERSE EVENTS OF SPECIAL INTEREST (AESI)

EPID Number: S O A - | | | | - | | | | - | | | | - | | | | |

Country - Province - District - Year - Case no

Today's date: D D / M M / Y Y Y Y

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

Date received	*Level*	*Signature*
	Private	
	District	
	Province	
	National EPI	
	National SAHPRA	

(For Office use only)

SECTION A: IDENTIFYING INFORMATION

Vaccine recipient name & surname: _____

If child: Caregiver's name & surname: _____

Vaccine recipient's residential address: _____

_____

Mobile no: _____ Telephone no: _____

Sex: ☐ M ☐ F ☐ Other *If applicable:* ☐ Pregnant ☐ Breastfeeding

Date of birth: D D / M M / Y Y Y Y

OR Age at onset: ☐☐ Years ☐☐ Months ☐☐☐ Days

OR Age group: ☐ 0 - <1 year ☐ 1 - 5 years ☐ >5 – 18 years ☐ >18 – 60 years ☐ >60 years

If applicable: Gestation: ☐ Full-term ☐ Premature

AESI Reporter's name & surname:

_____

Designation/Position:

_____

Institution & Department:

_____

_____

Telephone no: _____

Mobile no: _____

E-mail: _____

Date patient notified event to health system:
D D / M M / Y Y Y Y

SECTION B: ADVERSE EVENT(S)OF SPECIAL INTEREST (AESI)

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

Adverse event (s): (Tick (✓) all boxes that apply)

- ☐ Acute aseptic arthritis
- ☐ Acute cardiovascular injury
- ☐ Acute disseminated encephalomyelitis
- ☐ Acute liver injury
- ☐ Acute kidney injury
- ☐ Acute respiratory distress syndrome (Microangiopathy, Heart failure, Stress cardiomyopathy, Coronary artery disease Arrhythmia, Myocarditis)
- ☐ Anaphylaxis
- ☐ Anosmia, ageusia
- ☐ Chilblain-like lesions
- ☐ Coagulation disorder (Thromboembolism, Haemorrhage)
- ☐ Enhanced disease following immunisation
- ☐ Erythema multiforme
- ☐ Generalized convulsion
- ☐ Guillain Barré Syndrome
- ☐ Meningoencephalitis
- ☐ Multisystem inflammatory syndrome in children
- ☐ Single organ cutaneous vasculitis
- ☐ Thrombocytopenia
- ☐ Other (specify): _____

Describe vaccine recipient's AESI signs and symptoms. Use additional sheet if needed

_____

_____

_____

_____

Past medical history (including history of previous similar reactions or other allergies), concomitant medication and any other relevant information (e.g. other cases). Use additional sheet if needed

_____

_____

_____

_____

Patient name & surname: _____ EPID Number: _____

SECTION C: PRELIMINARY ASSESSMENT AND ACTIONS AT THE TIME OF REPORT

Did this AESI cause? ☐ Death ☐ Hospitalisation ☐ Disability ☐ Life threatening ☐ Other important medical events (Specify): _____

Outcome at the time of reporting: ☐ Recovering ☐ Recovered fully (no complications) ☐ Not Recovered ☐ Unknown

☐ Recovered with sequelae; Specify: _____

☐ Died ➔ Date of death: D D / M M / Y Y Y Y ➔ Full autopsy done: ☐ Yes ☐ No ☐ Unknown

If NO, verbal autopsy done? ☐ Yes ☐ No

☐ Hospitalisation ➔ Date of admission: D D / M M / Y Y Y Y

➔ Name of hospital: _____ Hospital number: _____

Did this person receive a COVID-19 vaccine? ☐ Yes ☐ No ☐ Unknown **If Yes, Complete Section E below**

SECTION D: VACCINE INFORMATION (Please attach a copy of the Vaccination Record)

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

Address / location: _____

COVID-19 vaccine administered								Diluent *(if applicable)*		
Vaccine given (Use trade name)	Manufacturer	Dose number (1st, 2nd)	Date vaccinated	Time vaccinated	Batch/ Lot number	Expiry date / Manufacture date	Immunisation record number	Batch/ Lot number	Expiry date	Date & time of reconstitution
Consumables used	**Needles**	Size: _____ Batch: _____ Expiry date: _____								
	Syringes	Size: _____ Batch: _____ Expiry date: _____								

Details of Non-COVID19 vaccines received in the last 1 year (Use additional page if there are more vaccines)

Consumables used (unless pre-filled)	**Needles**	Size: _____ Batch: _____ Expiry date: _____								
	Syringes	Size: _____ Batch: _____ Expiry date: _____								

SECTION E: FIRST DECISION MAKING LEVEL TO COMPLETE

For ALL AESI cases including COVID-19 vaccinated and unvaccinated

AEFI confirmation initiated: ☐ Yes ☐ No **If YES**, confirmation done by Dr/Mr/Ms _____

Date investigation planned: D D / M M / Y Y Y Y

Is this AESI linelisted? ☐ Yes ☐ No

For COVID-19 vaccinated cases: Field investigation planned with AESI investigation form? ☐ Yes ☐ No

If YES, date planned: D D / M M / Y Y Y Y

SECTION F: NATIONAL LEVEL TO COMPLETE

Date report received at National Level: D D / M M / Y Y Y Y | **AESI worldwide unique ID:** _____

Comments: _____

_____

IMPORTANT: Email this form within 24 hours to AEFI@health.gov.za

AND copy the EPI District Surveillance Officer

CONSENT CLAUSE FOR COLLECTION AND PROCESSING OF PERSONAL INFORMATION

By their signature below, 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) hereby provides consent to the collection and processing of their personal information (as set out in this Case Reporting Form) by the National Department of Health and third parties appointed by it (the "Department") for the purposes of investigating and assessing potential adverse events related to a vaccine/s received. 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) acknowledges that this information may be used i) to access all medical and clinical records for the purpose of 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 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 Department (AEFI@heath.gov.za) and the South African Health Products Regulatory Authority (adr@sahpra.org.za).

The Department undertakes to process the personal information contained in this Case Reporting Form, and collected during the process of 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 Department (AEFI@heath.gov.za).

Vaccine recipient: _____ (Name and Surname)

Signed by the vaccine recipient / relative / caregiver*

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

*Delete what is not applicable

health
Department: Health
REPUBLIC OF SOUTH AFRICA

ALL VACCINES including COVID-19

CASE REPORTING FORM (CRF) FOR ADVERSE EVENTS FOLLOWING IMMUNISATION (AEFI)

EPID Number: S O A - | | | | - | | | | - | | | | - | | | | |

Country - Province - District - Year - Case no

Today's date: D D / M M / Y Y Y Y

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

Date received	*Level*	*Signature*
	Private	
	District	
	Province	
	National EPI	
	National SAHPRA	

(For Office use only)

SECTION A: IDENTIFYING INFORMATION

NOTE: In maternal vaccination, if mother and baby / more than one baby are affected, complete separate form for each affected individual

Vaccine recipient name & surname: _____

If child: Caregiver's name & surname: _____

Vaccine recipient's residential address: _____

_____

Mobile no: _____ Telephone no: _____

Email: _____

Sex: ☐ M ☐ F ☐ Other *If applicable:* ☐ Pregnant ☐ Breastfeeding

Date of birth: D D / M M / Y Y Y Y

OR Age at onset: ☐☐ Years ☐☐ Months ☐☐☐ Days

OR Age group: ☐ 0 - <1 year ☐ 1 - 5 years ☐ >5 – 18 years ☐ >18 – 60 years ☐ >60 years

If applicable: Gestation: ☐ Full-term ☐ Premature

Reporter's name & surname:

_____

Designation/Position:

_____

Institution & Department:

_____

_____

Telephone no: _____

Mobile no: _____

E-mail: _____

Date patient notified event to health system:
D D / M M / Y Y Y Y

SECTION B: VACCINE INFORMATION (Please attach a copy of the Road to Health Booklet OR Vaccination Card)

NOTE: In the case of a foetal adverse event, ALSO record the mother's maternal vaccination details

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

Address / location: _____

Vaccine administered								**Diluent** *(if applicable)*		
Vaccine/s given (Use trade name)	**Date vaccinated**	**Time vaccinated**	**Dose number** (1st, 2nd)	**Batch/ Lot number**	**Expiry date / Manufacture date** (COVID-19)	**VVM Stage** (if applies)	**Manufacturer**	**Batch/ Lot number**	**Expiry date**	**Date & time of reconstitution**

Consumables used (unless pre-filled)	**Needles**	Size: _____ Batch: _____ Expiry date: _____
	Syringes	Size: _____ Batch: _____ Expiry date: _____

SECTION C: TRIGGER EVENTS

Date & time AEFI started: D D / M M / Y Y Y Y ☐☐ Hr ☐☐ Min ***Adverse event (s): (Tick (✓) all boxes that apply)***

Minor local reactions

☐ Swelling <5cm ☐ Induration / hardness
☐ Redness ☐ Rash
☐ Other (specify): _____

_____

Minor systemic reactions

☐ Excessive crying (infant) ☐ Mild fever <38°C
☐ Mild headache ☐ Mild body aches
☐ Mild pain (to touch / on movement, but not interfering with daily activities) ☐ Fainting
☐ Other (specify): _____

_____

Patient name & surname: _____ EPID Number: _____

Severe local reactions

- ☐ Pain, redness and/or swelling >3 days
- ☐ Swelling >5cm
- ☐ Swelling beyond nearest joint
- ☐ Lymphadenitis
- ☐ Abscess
- ☐ Necrosis at vaccination site
- ☐ Other (specify):

_____

_____

Severe systemic reactions

- ☐ Hospitalisation ☐ Death ☐ Collapse/ shock-like state
- ☐ Fever ≥38°C ☐ Thrombocytopenia ☐ Anaphylaxis
- ☐ Seizures ☐ Febrile ☐ Afebrile ☐ Encephalopathy ☐ Sepsis
- ☐ Toxic shock syndrome ☐ Vomiting ☐ Diarrhoea
- ☐ Other (specify): _____

Foetal adverse reactions in the case of maternal immunisation:

- ☐ Decreased FHR variability ☐ Decreased foetal movement ☐ Foetal death
- ☐ Onset of preterm labour, assessed to be possibly/probably related
- ☐ Foetal anomaly assessed to be possibly/probably related (e.g. congenital anomaly feasible with pre-pregnancy or 1st trimester immunisation)
- ☐ Foetus affected by maternal immunization (e.g. live vaccine administered to mother)

NOTE: Severe or serious adverse event ➔ Immediately notify District Office for Case Investigation

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

_____

_____

_____

_____

Were there any other similar AEFIs reported in the facility in the past 30 days? ☐ Yes ☐ No (If yes, specify)

_____

_____

SECTION D: PAST MEDICAL HISTORY

Past medical history (including history of previous similar reactions or other allergies), concomitant medication and dates of administration (exclude those used to treat reaction), any other relevant information. Use additional sheet if needed

_____

_____

_____

SECTION E: PRELIMINARY ASSESSMENT AND ACTIONS AT THE TIME OF REPORT

Is this event a serious AEFI? ☐ Yes ☐ No ***If Yes, tick (√) in the appropriate box below***

☐ Death ☐ Hospitalisation ☐ Disability ☐ Life threatening ☐ Congenital anomaly in off-spring of vaccine recipient

Comments: _____

SECTION F: WHAT WAS THE OUTCOME OF THE CASE FOLLOWING THE SUSPECTED AEFI in VACCINEE?

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

☐ Recovered with sequelae; Specify: _____

☐ 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: _____

SECTION G: FIRST DECISION MAKING LEVEL TO COMPLETE

Case investigation needed: ☐ Yes ☐ No

Date investigation planned: D D / M M / Y Y Y Y

District Office notified: ☐ Yes ☐ No

If yes, date notified: D D / M M / Y Y Y Y

SECTION H: NATIONAL LEVEL TO COMPLETE

Date report received at National Level: D D / M M / Y Y Y Y **AEFI worldwide unique ID:** _____

Comments: _____

IMPORTANT: Email this form within 24 hours to AEFI@health.gov.za

AND copy the EPI District Surveillance Officer

CONSENT CLAUSE FOR COLLECTION AND PROCESSING OF PERSONAL INFORMATION

By their signature below, 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) hereby provides consent to the collection and processing of their personal information (as set out in this Case Reporting Form) by the National Department of Health and third parties appointed by it (the "Department") for the purposes of investigating and assessing potential adverse events related to a vaccine/s received. 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) acknowledges that this information may be used i) to access all medical and clinical records for the purpose of 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 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 Department (AEFI@heath.gov.za) and the South African Health Products Regulatory Authority (adr@sahpra.org.za).

The Department undertakes to process the personal information contained in this Case Reporting Form, and collected during the process of 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 Department (AEFI@heath.gov.za).

Vaccine recipient: _____ (Name and Surname)

Signed by the vaccine recipient / relative / caregiver*

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

*Delete what is not applicable