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