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

Date received	Level	Signature
	Private	
	District	
	Province	
	National EPI	
	National SAHPRA	

(For Office use only)

Today's date: DD / MM / YYYY

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

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: ______________________________

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Mobile no: __________________ Telephone no: __________________

Email: ______________________________

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

Date of birth: DD / MM / YYYY

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:
DD / MM / YYYY

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: DD / MM / YYYY ☐☐ Hr ☐☐ Min ***Adverse event (s): (Tick (✓) all boxes that apply)***

Minor local reactions

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

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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): ______________________________

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Patient name & surname: ______________________________ EPID Number: ______________________________

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

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

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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

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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	District Office notified: ☐ Yes ☐ No
Date investigation planned: D D / M M / Y Y Y Y	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