CONFIDENTIAL

For national level office use only
BRN: _____ Initial / Follow- up

Ministry of Health, Brunei Darussalam

ADVERSE EVENT FOLLOWING IMMUNISATION (AEFI) REPORTING FORM

Please report **all** adverse events following immunisation. Do not hesitate to report if some details are not known. **MANDATORY FIELDS** are marked with *. **Identities of reporter and patient** will be kept confidential.

(1) PATIENT *

Patient name: _____ **Patient Address:** _____ **Telephone:** _____

Date of birth:_____ **Weight, if known (kg):** ___ **Gender:** ☐ **M** ☐ **F** **Pregnant** ☐ **Lactating** ☐ **Medical record no. / BruHims no.:**_____

Identity card no.:_____ **Nationality:** _____ **Ethnic group:** ☐ Malay ☐ Chinese ☐ Other (please specify):_____

(2) ADVERSE EVENT *

Serious: ☐ Yes ☐ No ***If yes (please tick all that apply):*** ☐ Death ☐ Life threatening ☐ Congenital abnormality ☐ Hospitalisation ☐ Disability ☐ Medically significant (please specify): _____

Adverse event(s) (please tick all that apply):

- ☐ Severe local reaction
  - ○ *>3days* ○ *Beyond nearest joint*
- ☐ Seizures
  - ○ *Febrile* ○ *Afebrile*
- ☐ Abscess
- ☐ Sepsis
- ☐ Encephalopathy
- ☐ Toxic shock syndrome
- ☐ Thrombocytopenia
- ☐ Anaphylaxis
- ☐ Fever≥38°C
- ☐ Others (please specify): _____

Date & Time AEFI started: _____ ☐☐ Hr ☐☐ Min

Treatment of AEFI: ☐ *Yes* ☐ *No* ***If yes*** (please specify): _____

Adverse event(s) of special interest (AESI) following Covid-19 vaccination (please tick all 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
- ☐ Generalised convulsion
- ☐ Guillain Barre Syndrome
- ☐ Meningoencephalitis
- ☐ Multisystem inflammatory syndrome in children
- ☐ Single Organ Cutaneous Vasculitis
- ☐ Thrombocytopenia
- ☐ Others (please specify): _____

Date & Time AESI started: _____ ☐☐ Hr ☐☐ Min

Treatment of AESI: ☐ *Yes* ☐ *No* ***If yes*** (please specify): _____

Outcome: ☐ Recovered ☐ Recovering ☐ Recovered with sequelae ☐ Not recovered ☐ Unknown ☐ Died (Date of Death): _____

☐ *Autopsy done:* ☐ *Yes* ☐ *No* ☐ *Unknown*

(3) SUSPECTED VACCINE *

Health facility (place vaccine administered): _____

Vaccine							Diluent (if applicable)			
Vaccine brand name, manufacturer & strength	**Date of vaccination**	**Time of vaccination**	**Route**	**Dose (1ST, 2ND, etc)**	**Batch/ Lot number**	**Expiry date**	**Name**	**Batch/ Lot number**	**Expiry date**	**Date and time of reconstitution**
1.										
2.										
3.										

(4) OTHER RELEVANT INFORMATION *(Additional pages may be attached)*

Past medical history (including history of similar reaction or other allergies), concomitant medication and dates of administration (exclude those used to treat reaction) and other relevant information (e.g. other cases, laboratory data, autopsy if conducted): _____

_____

(5) REPORTING OFFICER*

Reporter's Name: _____ Signature: _____

Designation & Department: _____ Institution Address: _____

Tel No: _____ Email: _____ Date patient notified event to health system: _____ Today's date: _____

(6) NATIONAL OFFICE USE ONLY

Date reporting form received: _____ **Investigation needed**: ☐ Yes ☐ No ***If yes, date investigation planned:*** _____

Comments: _____

CONFIDENTIAL

GUIDANCE ON AEFI REPORTING

WHAT TO REPORT?

An adverse event following immunisation (AEFI) is any untoward medical occurrence which follows immunisation, which does not necessarily have a causal relationship with the usage of the vaccine. An adverse event may be any unfavourable or unintended sign, abnormal laboratory finding, symptom or disease. Reported adverse events can either be true adverse events, i.e. really a result of the vaccine or immunisation process, or coincidental events that are not due to the vaccine or immunisation process but are temporally associated with immunisation.

HOW TO REPORT?

The AEFI Reporting form can be obtained from the National Adverse Drug Reaction Monitoring Centre and the nearest government pharmacy facility (hospital/ health centre). This form should be filled as completely as possible and returned to the address below or to the nearest government pharmacy facility (hospital/ health centre).

SUBMISSION OF FOLLOW-UP REPORTS

Any follow-up information for an AEFI that has already been reported can be sent to us in another form or *via* any other modes of reporting. Please state that it is a follow-up report, indicating the date and reference number of the initial report.

FOLD HERE FIRST

To:

National Adverse Drug Reaction Monitoring Centre (NADRMC)
c/o Pharmacovigilance Section
1st Floor, Department of Pharmaceutical Services Building
Simpang 433, Rimba Highway
Kg Madaras, Bandar Seri Begawan
BB1514
Brunei Darussalam
Telephone Number: +673 2392398/ 2393301 Ext 201, 206, 207
Fax Number: +673 2393097
E-mail: nadrmc.dps@moh.gov.bn

FOLD HERE SECOND