CONFIDENTIAL

HSA Health Sciences Authority

VACCINE ADVERSE EVENT (VAE) REPORT

Vigilance Branch • Health Products Regulation Group • Health Sciences Authority

HSA AE Watch (Adverse Events)

I PARTICULARS OF PATIENT

Name: .....

Identification no./NRIC: ..... Date of birth/Age: ..... Sex: ☐ Male ☐ Female

Ethnic group: ☐ Chinese ☐ Indian ☐ Malay ☐ Eurasian ☐ Others (Please specify): .....

II VACCINES ADMINISTERED RELATED TO ADVERSE EVENT

Suspected vaccine (Brand name)	Batch no.	Dose 1st / 2nd / 3rd / Booster	Route	Date given	Place of vaccination
1.					
2.					
3.					

Other vaccines/medications given at the same time and/or up to 3 months before (please specify dates given):

.....

.....

Other relevant information e.g. medical history, pregnancy, allergies, rechallenge (if performed):

.....

.....

III DETAILED ADVERSE EVENT INFORMATION

☐ Anaphylaxis ☐ Convulsion ☐ Encephalitis/Encephalopathy ☐ Guillain-Barré Syndrome

☐ Intussusception ☐ Thrombocytopenia ☐ Others*(Please specify): .....
E.g. abscess formation, paralysis, vasculitis.

**Non-serious reactions need not be reported e.g. fever <39°C, myalgia, local induration and pain.*

Please give details of the adverse event(s) including those listed above (please enclose relevant lab results):

.....

.....

.....

1. Onset date (dd/mm/yy) of event: ☐☐☐☐☐☐

2. Do you consider the event to be serious? ☐ Yes ☐ No

3. Hospitalisation following adverse event? ☐ Yes ☐ No

4. Treatment given? (Please specify): .....

5. Outcome: ☐ Recovered (Date): ..... ☐ Not yet recovered
☐ Fatal (Date of Death): ..... ☐ Unknown

IV PARTICULARS OF REPORTING PERSON

Name: ..... Profession: .....

Contact no: .....

Email address: .....

Date: .....

Name and address of place of practice	Signature

Please forward the completed form to: Vigilance Branch, Health Sciences Authority through **fax no: 6478 9069**. For any enquiries, please call **tel: 6866 1111**.

EXPLANATORY NOTES

CONFIDENTIALITY

Any information related to the identities of the reporter and patient will be kept confidential.

HSA encourages the reporting of all suspected serious adverse events to vaccines. In particular, please report the following:

All serious adverse events which:

a. are life-threatening or fatal,
b. require in-patient hospitalisation or prolong existing hospitalisation,
c. cause persistent incapacity or disability,
d. cause birth defect,
e. are medically significant.

Please do not be deterred from reporting because some details are not known. You may send the completed reporting form (additional pages may be attached if required) to:

Vigilance Branch
Health Products Regulation Group
Health Sciences Authority
11 Biopolis Way
#11-03 Helios
Singapore 138667

SUBMISSION OF FOLLOW-UP REPORTS

Please indicate that it is a follow-up report. It is very important that follow-up reports are identified and linked to the original report.

HOW TO REPORT





Mail	Fax	Phone	Email	E - reporting
Vigilance Branch **Health Products Regulation Group** **Health Sciences Authority** 11 Biopolis Way #11-03 Helios Singapore 138667	(65) 6478 9069	**(65) 6866 1111**	**HSA_productsafety@hsa.gov.sg**	**http://www.hsa.gov.sg/ae_online**