HSA
Health Sciences Authority

CONFIDENTIAL

SUSPECTED ADVERSE EVENTS

Safer Health Products Through Reporting

HSA AE Adverse Events Watch

I-PARTICULARS OF PATIENT

Name/initials: _____

NRIC/FIN/Passport no.: ☐☐☐☐☐☐☐☐☐

Age: _____ years Weight: _____ kg

Ethnic group: ☐ Chinese ☐ Indian ☐ Malay ☐ Eurasian

Sex: ☐ Female: ☐ Male

☐ Others(Please specify): _____

II-DETAILS OF ADVERSE EVENT (AE)

Date of onset: ☐☐☐☐☐☐ (d d / m m / y y)

Outcome: ☐ Recovered *(Date):* _____ ☐ Not yet recovered

☐ Fatal *(Date of death):* _____ ☐ Unknown

Sequelae (any permanent complications or injuries as a result of the AE):

☐ Yes ☐ No ☐ Unknown

Description of AE(s):

Suspected product(s) *(Please specify brand name if known. For vaccines, please indicate batch no.)*	Dosage regimen, including route *(e.g. PO 5 mg TDS, IV 1g stat, for vaccines: IM Dose 1/2/3/booster)*	Date started	Date stopped	Indication(s)
1.				
2.				
3.				
Concomitant products *(including complementary medicines consumed or vaccines administered at the same time and/or 3 months before)*				
1.				
2.				

Other relevant information: e.g. medical history, allergies, pregnancy, smoking, alcohol use, rechallenge (if performed). Please enclose any relevant laboratory results and photos of complementary health products, where applicable.

III-MANAGEMENT OF ADVERSE EVENT

Hospitalisation (following the AE): ☐ Yes ☐ No ☐ Already hospitalised before AE occurred

Do you consider the reaction to be serious? ☐ Yes ☐ No

If yes, please indicate why the reaction is considered to be serious (please tick ✓all that apply):

☐ Patient died due to reaction

☐ Life threatening

☐ Congenital anomaly

☐ Involved or prolonged inpatient hospitalisation

☐ Involved persistent or significant disability or incapacity

☐ Medically significant, please give details: _____

Treatment given: ☐ Yes ☐ No (if yes, please specify): _____

Relation of product to adverse event?

☐ Certain ☐ Probable ☐ Possible ☐ Unlikely ☐ Unconfirmed

IV-PARTICULARS OF REPORTER

Name: _____ Signature: _____

Profession: _____ Date: _____

Contact no: _____ Email address: _____

Name and address of place of practice

Ref No. (for official use)

☐☐☐☐☐☐☐☐☐

EXPLANATORY NOTES

CONFIDENTIALITY

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

WHAT TO REPORT

An Adverse Event (AE) is defined as a reaction which is noxious (harmful) and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis, or treatment of a disease, or for the modification of a physiological function.

HSA encourages the reporting of all suspected adverse events to health products (including herbal, traditional or alternative remedies). In particular, please report the following:

1. All serious adverse events which:
    a. are life threatening or fatal,
    b. require inpatient hospitalisation or prolong existing hospitalisation,
    c. cause persistent incapacity or disability,
    d. cause birth defect,
    e. are medically significant.

2. All adverse events to recently marketed health products that have been introduced into Singapore in the recent 5 years, regardless of their nature and severity.

Please do not be deterred from reporting because some details are not known. You may send the completed AE Report Form (through your respective hospital pharmacies, if applicable) to the Vigilance and Compliance Branch, Health Products Regulation Group (see below for full address). Additional pages may be attached if required.

SUBMISSION OF FOLLOW-UP REPORTS

Any follow-up information for an AE that has already been reported can be sent to us on another form or via any other modes of reporting. 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 to:
Vigilance & Compliance Division
Medicinal Products Cluster
Integrated Health Regulation Group (IHRG)
Health Sciences Authority
11 Biopolis Way
#11-03 Helios
Singapore 138667



Phone: ***(65) 6866 1111***



Email: ***HSA_productsafety@hsa.gov.sg***



Online Reporting:
http://www.hsa.gov.sg/adverse-events

HSA Health Sciences Authority

Vigilance & Compliance Division Integrated Health Regulation Group (IHRG)
Health Sciences Authority
11 Biopolis Way, #11-03, Helios, Singapore 138667
http://www.hsa.gov.sg