

SUSPECTED ADVERSE DRUG REACTIONS

Safer Medicines Through Reporting

I-PARTICULARS OF PATIENT

Patient's initials: _____

 Record no./NRIC/Passport no.:

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Age: _____ years Weight: _____ kg

 Ethnic group: Chinese Indian Malay Eurasian

 Sex: Female Male

 Others (Please specify): _____

II-DETAILS OF ADVERSE DRUG REACTION (ADR)

 Date of onset:

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 (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 ADR):

 Yes No Unknown

Description of ADR(s):

Suspected drug(s) <i>(Please specify brand name if known. For vaccines, please indicate batch no.)</i>	Dosage	Frequency	Route	Date started	Date stopped	Indication(s) for using drug
1.						
2.						
3.						

Other drugs (including complementary medicines, consumed at the same time and/or 3 months before)

1.						
2.						
3.						
4.						
5.						

Other relevant information: e.g. medical history, allergies, pregnancy, smoking, alcohol use, rechallenge (if performed). Please enclose any relevant laboratory results.

III-MANAGEMENT OF ADVERSE REACTION

 Hospitalisation (following the ADR): Yes No Already hospitalised before ADR 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):

- | | |
|---|--|
| <input type="checkbox"/> Patient died due to reaction | <input type="checkbox"/> Involved or prolonged in-patient hospitalisation |
| <input type="checkbox"/> Life threatening | <input type="checkbox"/> Involved persistent or significant disability or incapacity |
| <input type="checkbox"/> Congenital anomaly | <input type="checkbox"/> Medically significant, please give details: _____ |

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

IV-PARTICULARS OF REPORTER

Name and address of place of practice

Name: _____ Signature: _____

Profession: _____ Date: _____

Contact no: _____ Email address: _____

Ref No. (for official use)

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EXPLANATORY NOTES

CONFIDENTIALITY

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

WHAT TO REPORT

An Adverse Drug Reaction (ADR) 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 reactions to drugs and other medicinal substances (including herbal, traditional or alternative remedies). In particular, please report the following:

1. All serious adverse drug reactions 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.
2. All adverse drug reactions to recently marketed drugs 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 ADR Report Form (through your respective hospital pharmacies, if applicable) to the Vigilance 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 ADR that has already been reported can be sent to us in 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:

**Adverse Event Management Unit
Vigilance Branch
Health Products Regulation Group
Health Sciences Authority**
**11 Biopolis Way
#11-03, Helios
Singapore 138667**



Fax: **(65) 6478 9069**



Phone: **(65) 6866 1111**



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



Online Reporting:

http://www.hsa.gov.sg/adr_online

*The form can be downloaded from
http://www.hsa.gov.sg/adr_form*