

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 3538**



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***