

INCIDENT REPORTING POLICIES:

7.2 ADVERSE DRUG REACTION REPORTING

POLICY

All suspected adverse drug reactions (ADRs) reported to the pharmacy department or identified by a pharmacist will be investigated by a clinical pharmacist. All serious ADRs will be FAXED to the Canada Vigilance Program (CVP) at 1-866-678-6789.

A serious adverse drug reaction is defined by the Food and Drug regulations as "a noxious and unintended response to a drug that occurs at any dose and that requires in-patient hospitalization or prolongation of existing hospitalization, causes congenital malformation, results in persistent or significant disability or incapacity, is life-threatening or results in death".

PROCEDURE

1. All suspected ADRs should be reported on the "Canada Vigilance Adverse Reaction Reporting Form". This form is found in the CPS in Appendix 4 at the back of the book, or on-line at:
http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/medeff/report-declaration/arei_form-eng.pdf
2. Any health professional can fill out an ADR form.
3. When a suspected ADR is reported to the pharmacy department or identified by a pharmacist, an ADR report form will be completed by a clinical pharmacist.
4. To make it easier for Vancouver staff, a link on the VHnet "Clinical" tab has been created:
<http://teamsites/sites/vchforms/Lists/AdverseDrugReaction/ADRReportingForm.aspx>
Accessing this link will provide all the necessary information fields for the CVP report. Once submitted, the VGH Medication Safety pharmacist will be notified by email so that the report can be reviewed and then sent to CVP.
5. Completed ADR report forms will be FAXED to the Canada Vigilance Program at 1-866-678-6789. The original will be filed in the ADR file in the Pharmacy.