ADVERSE DRUG REACTIONS – SERIOUS AND LIFE-THREATENING (ADR)

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REPORTING INFORMATION
(To be completed by the CPSP Senior Coordinator)
Report number:
Month of reporting:
Province:
Today's date:

Please complete the following sections for the case identified above.
Patient and reporter information will be kept confidential.

CASE DEFINITION FOR ADVERSE DRUG REACTIONS – SERIOUS AND LIFE-THREATENING

Serious and life-threatening adverse drug reactions (ADRs)* in an infant or child 18 years or less, associated with the use of prescription, non-prescription, biological (immunoglobulins) products, complementary medicines (including herbals), and radio-pharmaceutical products.

Report even if you are not certain if the product caused the adverse reaction or you do not have all the reporting details.

Exclusions: Do not report reactions due to medical devices, blood products (platelets, red cells, single donor plasma), vaccines, poisonings or self-administered overdoses.

* **Noxious and unintended severe** response to a drug which occurs at any dose and results in emergency observation, hospitalization, persistent or significant disability, or death.

SECTION 1 – PATIENT INFORMATION

1.1 Date of birth: ____ /_____ /_____
DD MM YYYY

1.2 Height: _____ inches or _____ cm

1.3 Weight: _____ lbs or _____ kg

1.4 Country of family ancestry
Mother: _____ Father: _____

1.5 Race: _____

1.6 Sex: Male ___ Female ___

SECTION 2 – ADVERSE REACTION

2.1 Describe reaction (including site of reaction): _____
_____

2.2 Date of reaction: ____ /_____ /_____
DD MM YYYY

2.3 Causality of ADR – The drug was the: possible cause ___ or probable cause ___ or definite cause ___

SECTION 3 – SUSPECTED DRUG PRODUCT(S)

3.1 Name (give labeled strength and manufacturer, if known)
_____

3.2 Dose, frequency and route used
Dose _____ Frequency _____
Route used: Oral__ IV__ IM__ SC__ Other__

3.3 Therapy dates (if unknown, give duration)
From ____ /____ /_____ to ____ /____ /_____
DD MM YYYY DD MM YYYY
Duration _____

3.4 Indication for use of suspected drug product:
_____

SECTION 3A – SUSPECTED DRUG PRODUCT(S)
Complete if a second drug is involved

3.1A Name (give labeled strength and manufacturer, if known)
_____

3.2A Dose, frequency and route used
Dose _____ Frequency _____
Route used: Oral__ IV__ IM__ SC__ Other__

3.3A Therapy dates (if unknown, give duration)
From ____ /____ /_____ to ____ /____ /_____
DD MM YYYY DD MM YYYY
Duration _____

3.4A Indication for use of suspected drug product:
_____

SECTION 3 – SUSPECTED DRUG PRODUCT(S) (cont'd)

3.5 Did the reaction abate after use stopped or dose reduced? Yes ___ No ___ Doesn't apply ___
Please specify: _____

3.6 Did the reaction reappear after reintroduction of the drug? Yes ___ No ___ Doesn't apply ___

SECTION 4 – TESTS / LABORATORY DATA INVESTIGATIONS

4.1 Relevant tests / laboratory data, including dates (DD/MM/YYYY)

SECTION 5 – TREATMENT

5.1 Treatment of adverse reaction (drugs and/or therapy), including dates (DD/MM/YYYY)

5.2 Concomitant drugs, including herbal products, complimentary medicines, etc. (exclude treatment of reaction)

Name	**Dose**	**Frequency**	**Route**	**Therapy dates** from (DD/MM/YYYY) to (DD/MM/YYYY)

5.3 Other relevant history, including preexisting medical conditions (e.g., allergies, hepatic/renal dysfunction, chronic conditions, pregnancy, smoking and alcohol use).

5.4 Has any other family member had an adverse reaction to this medication? Yes ___ No ___
If yes, please specify: _____
_____

SECTION 6 – OUTCOME

6.1 Outcome attributed to adverse reaction (check all that apply)

Length of time from onset to fatal reaction _____
Life-threatening _____ Hospitalization _____ Hospitalization prolonged due to ADR _____
Disability _____ Required intervention to prevent damage/permanent impairment _____
Other: _____

6.2 Describe details of outcome (e.g., length of hospitalization, type of disability, etc.)

Not yet recovered ____

SECTION 7 – GENERAL INFORMATION

7.1 Have you reported this particular ADR case previously? Yes ___ No ___
If yes, please specify: _____
_____

SECTION 8 – REPORTING PHYSICIAN

First name_____ Surname_____

Address_____

City_____ Province/Territory_____ Postal code_____

Telephone number_____ Fax number_____

E-mail_____ Date completed_____

Thank you for completing this form.

(ADR 2003-01)